

**PRESIDENT'S FISCAL YEAR 2011 BUDGET FOR  
THE DEPARTMENT OF HEALTH AND HUMAN  
SERVICES**

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**HEARING**  
BEFORE THE  
**COMMITTEE ON ENERGY AND  
COMMERCE**  
**HOUSE OF REPRESENTATIVES**  
ONE HUNDRED ELEVENTH CONGRESS  
SECOND SESSION

\_\_\_\_\_  
FEBRUARY 4, 2010  
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# **PRESIDENT'S FISCAL YEAR 2011 BUDGET FOR THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**THURSDAY, FEBRUARY 4, 2010**

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON ENERGY AND COMMERCE,  
*Washington, DC.*

The committee met, pursuant to call, at 2:15 p.m., in Room 2123, Rayburn House Office Building, Hon. Henry A. Waxman [chairman of the committee] presiding.

Present: Representatives Waxman, Dingell, Markey, Pallone, Gordon, Rush, Eshoo, Engel, Green, DeGette, Capps, Harman, Schakowsky, Gonzalez, Weiner, Butterfield, Melancon, Barrow, Matsui, Christensen, Castor, Sarbanes, Space, McNerney, Sutton, Braley, Barton, Upton, Deal, Whitfield, Shimkus, Shadegg, Blunt, Buyer, Pitts, Bono Mack, Terry, Myrick, Murphy of Pennsylvania, Burgess, Blackburn, Gingrey and Scalise.

Staff Present: Phil Barnett, Staff Director; Kristin Amerling, Chief Counsel; Bruce Wolpe, Senior Advisor; Karen Nelson, Deputy Committee Staff Director for Health; Andy Schneider, Chief Health Counsel; Rachel Sher, Counsel; Jack Ebeler, Senior Advisor on Health Policy; Brian Cohen, Senior Investigator and Policy Advisor; Robert Clark, Policy Advisor; Elana Stair, Policy Advisor; Katie Campbell, Professional Staff Member; Tim Gronniger, Professional Staff Member; Virgil Miller, Professional Staff Member; Anne Morris, Professional Staff Member; Alvin Banks, Special Assistant; Allison Corr, Special Assistant; Eric Flamm, FDA Detailee; Camille Sealy, Fellow; Andrew Bindman, Fellow (Robert Wood Johnson); Karen Lightfoot, Communications Director, Senior Policy Advisor; Lindsay Vidal, Special Assistant; Earley Green, Chief Clerk; Jen Berenholz, Deputy Clerk; Mitchell Smiley, Special Assistant; Matt Eisenberg, Staff Assistant; Mark Noble, Director of New Media; David Cavicke, Minority Chief of Staff; Katie Wheelbarger, Minority Deputy Chief of Staff; Amanda Mertens Campbell, Minority General Counsel; Brandon Clark, Minority Professional Staff Member; Marie Fishpaw, Minority Professional Staff Member; Ryan Long, Minority Counsel; Aarti Shah, Minority Counsel; Clay Alspach, Minority Counsel; Melissa Bartlett, Minority Counsel; Will Carty, Minority Professional Staff Member; Peter Kielty, Minority Legislative Analyst; and Cedric James, Minority Legislative Analyst.

**OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA**

Mr. WAXMAN. The meeting will come to order.

This afternoon we will hear from the distinguished Secretary of the Department of Health and Human Services, Kathleen Sebelius. She will testify on the health proposals in the President's fiscal year 2011 budget for which her department has responsibility.

This responsibility is daunting. The department she leads has a budget of over \$900 billion in fiscal year 2011. The programs that her department administers will directly affect the Nation's public health and will ensure access to needed health care to over 100 million Americans enrolled in Medicare, Medicaid, and the Child Health Insurance Program.

As President Obama reminded us on Monday, our Nation is at war, and our economy has lost 7 million jobs over the last 2 years. The deficit that greeted this administration stood at \$1.3 trillion. Successful efforts over the past year to rescue the economy and the financial system from collapse have unavoidably added to that deficit.

We clearly need to solve the deficit problem, but we can't do it overnight, and the President's budget wisely does not try to do so. The budget strikes a careful balance, helping unemployed families by creating jobs and protecting them against the loss of health insurance, investing in next-generation health care technologies, and taking steps to reduce the deficit while protecting the most important investments.

In the health area, the President's budget recognizes that certain investments are essential while the economic recovery is still underway. The budget supports the enactment of health reform, which will provide affordable coverage for over 30 million uninsured Americans while we reducing the unsustainable rate of increase in health care costs. The budget recognizes the need to protect the ability of America's seniors to see their doctors by repairing Medicare's physician payment system. The budget provides additional help to States that are struggling to maintain their Medicaid programs in the face of increased demand and reduced revenues.

The budget increases funding for community health centers to provide cost-effective primary care, and it invests in prevention and wellness activities to improve the Nation's health and to reduce the need for expensive medical care. The budget increases resources for FDA that will enable the agency to improve its oversight of medical products, strengthen its food safety efforts, and implement its new responsibility for tobacco.

It is the duty of Congress to consider the President's budget proposals as it makes its spending and revenue decisions for the coming fiscal year. Secretary Sebelius is here to assist the members of this committee in carrying out that responsibility by giving us a better understanding of the proposals and their rationale. Through this conversation, we can together make Federal health programs work as effectively and efficiently as possible. I look forward to hearing from her.

I want to recognize for the purpose of an opening statement the ranking member of the committee, Mr. Barton, for 5 minutes.  
[The prepared statement of Mr. Waxman follows:]

**Opening Statement of Rep. Henry A. Waxman  
Chairman, Committee on Energy and Commerce  
“Secretary Kathleen Sebelius: The President’s Fiscal Year  
2011 Budget”  
February 4, 2010**

This afternoon, we will hear from the distinguished Secretary of the Department of Health and Human Services, Kathleen Sebelius. She will testify on the health proposals in the President’s Fiscal Year 2011 Budget for which her Department has responsibility.

This responsibility is daunting. The Department she leads has a budget of over \$900 billion in FY 2011. The programs that her Department administers will directly affect the nation’s public health and will ensure access to need health care by over 100 million Americans enrolled in Medicare, Medicaid, and the Child Health Insurance Program.



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In the health area, the President's budget recognizes that certain investments are essential while the economic recovery is still underway:

- The budget supports the enactment of health reform, which will provide affordable coverage for over 30 million uninsured Americans while reducing the unsustainable rate of increase in health care costs.
- The budget recognizes the need to protect the ability of America's seniors to see their doctors by repairing Medicare's physician payment system.
- The budget provides additional help to states that are struggling to maintain their Medicaid programs in the face of increased demand and reduced revenues.
- The budget increases funding for community health centers to provide cost-effective primary care, and it invests in prevention and wellness activities to improve the nation's health and to reduce the need for expensive medical care.

- The budget increases resources for FDA that will enable the agency to improve its oversight of medical products, strengthen its food safety efforts, and implement its new responsibilities for tobacco.

It is the duty of Congress to consider the President's budget proposals as it makes its spending and revenue decisions for the coming fiscal year.

Secretary Sebelius is here to assist the Members of this Committee in carrying out that responsibility by giving us a better understanding of the proposals and their rationale.

Through this conversation, we can together make federal health programs work as effectively and efficiently as possible. I look forward to learning from her.

Mr. BARTON. Mr. Chairman, before I do that, I have a parliamentary inquiry.

Mr. WAXMAN. The gentleman will make his parliamentary inquiry.

Mr. BARTON. What is the position of the Chair for today's hearing in terms of opening statements by Members on both sides of the aisle?

Mr. WAXMAN. We will divide the opening statements equally between the Chair of the full committee, the Chair of the subcommittee, the ranking member of the full committee, and the ranking member of the subcommittee. And we will then go right to the hearing with the Secretary. After that, every member will have an opportunity for 5 minutes. They can use that for their statements, they can use that for questions, they can use it however they see fit. But under the rules adopted by the committee, we anticipated that there would be an occasion like this where, while we ordinarily like to let members have opening statements, we just can't accommodate all the members that would like to make opening statement and be able to get to the Secretary and meet everybody's schedule. I regret that. We have made accommodations notwithstanding the rules on a number of other occasions, but we are going to have to stick tight to the rules at this time.

Mr. BARTON. Mr. Chairman, so what you are saying is that the only members that can make an opening statement are the chairman, the subcommittee chairman, the ranking member of the full committee and the subcommittee, and no other member; is that correct?

Mr. WAXMAN. Yes. And that would include Mr. Dingell, which we have always done in all of our hearings.

Mr. BARTON. Based on that, Mr. Chairman, I would move to postpone the hearing.

Mr. WAXMAN. There is a motion before us to postpone the hearing. All those in favor of the motion say aye. Aye. All those opposed say no. No. The nos have it, the motion is not agreed to.

Mr. BARTON. Mr. Chairman, on that, I would request a roll call vote.

Mr. WAXMAN. I would like to ask the gentleman to refrain from doing that. We do have the Secretary here. We try to accommodate you. We are not doing this out of any malice or meanness, but we tried to accommodate Dr. Burgess in his request, we have tried to accommodate people with opening statements. Usually we try to get the meeting started earlier so we can do opening statements; we are not able to do that today. And I think it is self-defeating.

Mr. BARTON. I opposed the rule that you implemented——

Mr. WAXMAN. But you lost.

Mr. BARTON. We did lose, but I have the right to request a roll call vote, and I am going to do that. And that is in the rules. But if you have chosen to not do it, then we are going to use the rules that we have. I am going to request a roll call vote.

Mr. WAXMAN. The gentleman requests a roll call vote. The Chair is going to inquire of the parliamentarian if this motion——

The Clerk will call the roll.

The CLERK. Mr. Waxman?

Mr. WAXMAN. No.

The CLERK. Mr. Waxman votes no.  
 Mr. Dingell?  
 [No response.]  
 The CLERK. Mr. Markey?  
 [No response.]  
 The CLERK. Mr. Boucher?  
 [No response.]  
 The CLERK. Mr. Pallone?  
 Mr. PALLONE. No.  
 The CLERK. Mr. Pallone votes no.  
 Mr. Gordon?  
 Mr. GORDON. No.  
 The CLERK. Mr. Gordon votes no.  
 Mr. Rush?  
 [No response.]  
 The CLERK. Ms. Eshoo?  
 Ms. ESHOO. No.  
 The CLERK. Ms. Eshoo votes no.  
 Mr. Stupak?  
 [No response.]  
 The CLERK. Mr. Engel?  
 Mr. ENGEL. No.  
 The CLERK. Mr. Engel votes no.  
 Mr. Green?  
 Mr. GREEN. No.  
 The CLERK. Mr. Green votes no.  
 Ms. DeGette?  
 Ms. DEGETTE. No.  
 The CLERK. Ms. DeGette votes no.  
 Mrs. Capps?  
 Mrs. CAPPS. No.  
 The CLERK. Mrs. Capps votes no.  
 Mr. Doyle?  
 [No response.]  
 The CLERK. Ms. Harman?  
 Ms. HARMAN. No.  
 The CLERK. Ms. Harman votes no.  
 Ms. Schakowsky?  
 Ms. SCHAKOWSKY. No.  
 The CLERK. Ms. Schakowsky votes no.  
 Mr. Gonzalez?  
 Mr. GONZALEZ. No.  
 The CLERK. Mr. Gonzalez votes no.  
 Mr. Inslee?  
 [No response.]  
 The CLERK. Ms. Baldwin?  
 [No response.]  
 The CLERK. Mr. Ross?  
 [No response.]  
 The CLERK. Mr. Weiner?  
 [No response.]  
 The CLERK. Mr. Matheson?  
 Mr. MATHESON. No.  
 The CLERK. Mr. Matheson votes no.

Mr. Butterfield?  
 Mr. BUTTERFIELD. No.  
 The CLERK. Mr. Butterfield votes no.  
 Mr. Melancon?  
 Mr. MELANCON. No.  
 The CLERK. Mr. Melancon votes no.  
 Mr. Barrow?  
 Mr. BARROW. No.  
 The CLERK. Mr. Barrow votes no.  
 Mr. Hill?  
 [No response.]  
 The CLERK. Ms. Matsui?  
 Ms. MATSUI. No.  
 The CLERK. Ms. Matsui votes no.  
 Mrs. Christensen?  
 [No response.]  
 The CLERK. Ms. Castor?  
 Ms. CASTOR. No.  
 The CLERK. Ms. Castor votes no.  
 Mr. Sarbanes?  
 Mr. SARBANES. No.  
 The CLERK. Mr. Sarbanes votes no.  
 Mr. Murphy of Connecticut?  
 [No response.]  
 The CLERK. Mr. Space?  
 [No response.]  
 The CLERK. Mr. McNerney?  
 [No response.]  
 The CLERK. Ms. Sutton?  
 Ms. SUTTON. No.  
 The CLERK. Ms. Sutton votes no.  
 Mr. Braley?  
 Mr. BRALEY. No.  
 The CLERK. Mr. Braley votes no.  
 Mr. Welch?  
 [No response.]  
 The CLERK. Mr. Barton?  
 Mr. BARTON. Aye.  
 The CLERK. Mr. Barton votes aye.  
 Mr. Hall?  
 [No response.]  
 The CLERK. Mr. Upton?  
 Mr. UPTON. Aye.  
 The CLERK. Mr. Upton votes aye.  
 Mr. Stearns?  
 [No response.]  
 The CLERK. Mr. Deal?  
 Mr. DEAL. Aye.  
 The CLERK. Mr. Deal votes aye.  
 Mr. Whitfield?  
 Mr. WHITFIELD. Aye.  
 The CLERK. Mr. Whitfield votes aye.  
 Mr. Shimkus?  
 Mr. SHIMKUS. Aye.

The CLERK. Mr. Shimkus votes aye.  
 Mr. Shadegg?  
 [No response.]  
 The CLERK. Mr. Blunt?  
 Mr. BLUNT. Aye.  
 The CLERK. Mr. Blunt votes aye.  
 Mr. Buyer?  
 Mr. BUYER. Aye.  
 The CLERK. Mr. Buyer votes aye.  
 Mr. Radanovich?  
 [No response.]  
 The CLERK. Mr. Pitts?  
 Mr. PITTS. Aye.  
 The CLERK. Mr. Pitts votes aye.  
 Mrs. Bono Mack?  
 Mrs. BONO MACK. Aye.  
 The CLERK. Mrs. Bono Mack votes aye.  
 Mr. Walden?  
 [No response.]  
 The CLERK. Mr. Terry?  
 Mr. TERRY. Aye.  
 The CLERK. Mr. Terry votes aye.  
 Mr. Rogers?  
 [No response.]  
 The CLERK. Mrs. Myrick?  
 Mrs. MYRICK. Aye.  
 The CLERK. Mrs. Myrick votes aye.  
 Mr. Sullivan?  
 [No response.]  
 The CLERK. Mr. Murphy of Pennsylvania?  
 Mr. MURPHY of Pennsylvania. Aye.  
 The CLERK. Mr. Murphy of Pennsylvania votes aye.  
 Mr. Burgess?  
 Dr. BURGESS. Aye.  
 The CLERK. Mr. Burgess votes aye.  
 Mrs. Blackburn?  
 Mrs. BLACKBURN. Aye.  
 The CLERK. Mrs. Blackburn votes aye.  
 Mr. Gingrey?  
 Mr. GINGREY. Aye.  
 The CLERK. Mr. Gingrey votes aye.  
 Mr. Scalise?  
 Mr. SCALISE. Aye.  
 The CLERK. Mr. Scalise votes aye.  
 Mr. Rush?  
 Mr. RUSH. No.  
 The CLERK. Mr. Rush votes no.  
 The CLERK. Mr. Weiner.  
 Mr. WEINER. No.  
 The CLERK. Mr. Weiner votes no.  
 Mr. Space?  
 Mr. SPACE. No.  
 The CLERK. Mr. Space votes no.  
 Mr. Dingell?

Mr. DINGELL. No.

The CLERK. Mr. Dingell votes no.

Mr. Markey?

Mr. MARKEY. No.

The CLERK. Mr. Markey votes no.

Mr. Shadegg?

Mr. SHADEGG. Aye.

The CLERK. Mr. Shadegg votes aye.

The CLERK. Mr. McNerney?

Mr. MCNERNEY. No.

The CLERK. Mr. McNerney votes no.

Mr. WAXMAN. Have all members responded? The clerk will count the votes and announce them.

The CLERK. On this vote, Mr. Chairman, the ayes are 17, the nays are 25.

Mr. WAXMAN. 17 ayes, 25 noes. The motion is not agreed to.

Mr. Barton, do you wish to have an opening statement?

Mr. BARTON. I wish to have another parliamentary inquiry based on my opening statement.

Mr. WAXMAN. The gentleman will state his parliamentary inquiry.

Mr. BARTON. Under the Chairman's prerogative, you are not allowing opening statements except for two members on each side, the Chair, the subcommittee Chair, the ranking member of the full and the subcommittee.

Mr. WAXMAN. And Mr. Dingell.

Mr. BARTON. And Mr. Dingell. Within that group, are members allowed to sublease their time? For example, if I don't want to use my 5 minutes, can I sublease 1 minute to Dr. Gingrey and 1 minute to Dr. Burgess under your ruling, as long as I don't take more than 5 minutes total?

Mr. WAXMAN. I have no objection if you want to use your time and distribute it to other members, but we have to stay within the time.

Mr. GREEN. Mr. Chairman, parliamentary inquiry.

Mr. WAXMAN. The gentleman will state his parliamentary inquiry.

Mr. GREEN. Mr. Chairman, I understood that when each of us get our 5 minutes, we can either make a statement or we can ask questions.

Mr. WAXMAN. Absolutely. That is, of course, after the Secretary testifies.

Mr. GREEN. I just wanted to make sure that we will have the chance to either make a statement or ask questions. Thank you.

Mr. WAXMAN. Without objection, the Chair will yield to Mr. Barton his 10 minutes—your 5 minutes.

Mr. BARTON. I will take 10, Mr. Chairman.

Mr. WAXMAN. We will yield to you your 5 minutes.

Mr. BARTON. I will take 20 if you will give me 20.

Mr. WAXMAN. Well, you have already taken a lot of time.

Mr. BARTON. Well, I think it is important that members on both sides, Mr. Chairman, have the right—

Mr. WAXMAN. The gentleman is recognized for 5 minutes; it is his time to do with as he sees fit.



**OPENING STATEMENT OF HON. JOE BARTON, A  
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. BARTON. All right. I will make this statement: The little exercise that we just went through is to give every member of this committee an opportunity to talk to the President's designee for health care before she gives her opening statement. I think that is important for every member of this committee on both sides of the aisle. I strongly disagree with the rule that was implemented at the start of this Congress. I can't prevent its implementation because the majority did vote to give Chairman Waxman that power and he has used it; I think he has used it mistakenly, but he does have the right to do that.

Having said that, Mr. Chairman, we are delighted to have our Secretary of Health and Human Services before us. We have received the President's budget and we understand that she is prepared to explain that budget. We also hope that she will be willing to answer some questions about what the President intends to do in terms of his health care policy given what has happened in Massachusetts and in the other body.

With that, I would be happy to yield to Dr. Gingrey for 1 minute if he would wish to make a brief opening statement.

Mr. GINGREY. Mr. Chairman, I thank the gentleman for yielding. Madam Secretary, I thank you for being here.

The President's \$911 billion budget request for the Department of HHS represents a 10 percent increase in spending over last year's budget. While there are some laudable things included in this proposal, this budget rests on cutting \$500 billion from the Medicare program. These cuts, according to, Madam Secretary, your chief actuary of the Medicare program, will "result in less generous benefits, and might result in physicians who treat Medicare seniors ending their participation in the program."

Eleven million seniors are enrolled in Medicare Advantage plans, roughly a quarter of all Medicare beneficiaries are at considerable risk, and they will incur hundreds of dollars in annual cost increases to make up for these cuts. Trimming the fat from the program is one thing, but gutting the program is certainly another.

Mr. Chairman, let me say again, our seniors' health care program and their pocketbooks should not be used as a piggy bank to fund a government one-size-fits-all takeover of our health care system.

I yield back the time and I thank the gentleman for yielding.

Mr. BARTON. I now want to yield to the vice ranking member, Mr. Blunt of Missouri, for 1 minute.

Mr. BLUNT. Thank you, Mr. Barton, for yielding to me.

Frankly, Mr. Barton and members of the committee, I think this budget does not accurately reflect our current economic situation. The so-called "spending freeze" doesn't even go into effect until next year. The budget has a complete lack of detail when it comes to Medicare cost containment, much less detail than the budget the President submitted last year.

There are also discrepancies that make the administration's goals unclear because this budget seems to assume that health care reform would already be enacted. I would be interested particularly to hear why high-risk pools are excluded from the budget and what

the administration's plans for these programs will be. Currently, this program serves thousands of Missourians that otherwise would be uninsured. I would like to see it expanded rather than eliminated from the budget. I hope to learn today that that is not the goal of the budget, even though the budget excludes high-risk programs.

I yield back.

Mr. BARTON. Is there anybody else on my final 1½ minutes that wishes to say something before I finish up? Seeing no hands raised, let me conclude my time, Mr. Chairman, by simply saying that when the President was sworn into office, at our first meeting in the White House he promised a health care reform package that wouldn't add one net dime to the national debt. As we all know, the plan that has come out of the Congress, or at least out of the House, is a huge unfunded mandate. In this particular budget that has been presented, it appears that there will be even more spending on health care. We don't see how that is reconcilable. We do know that over 60 percent of the population in this country has expressed their disapproval of the plan that is languishing, the different plans in the House and the Senate. We would hope, Mr. Chairman and Madam Secretary, that the President will reach out to everybody on both sides of the aisle, start over and deliver an honest, bipartisan effort to try to get a health care plan that is affordable, that is real reform, and it does provide more health care for more Americans.

With that, Mr. Chairman, I yield back the remaining 10 seconds of my time.

Mr. WAXMAN. The gentleman yields back his time.

Mr. Pallone.

**OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY**

Mr. PALLONE. Thank you, Mr. Chairman.

I want to welcome the Secretary here this afternoon. We always enjoy it when you visit the committee.

It is often said that budgeting is about setting priorities: how do we allocate our resources to those things that we value? And this is no easy task especially amid concerns of rising deficits and debt. But it is clear to me that based on the President's budget proposal, health care remains a top priority for this administration. I am happy that this is the case because as we all know the health care problems that American families face are getting worse and need our attention.

Millions of Americans have lost their jobs amid the recession and with it access to their employer-sponsored health insurance. In order to help provide some relief to these families, last year we passed the American Reinvestment and Recovery Act, which included additional money to help maintain State Medicaid programs in the face of increasing enrollment and fewer State dollars. In addition, we provided laid-off workers with a new 65 percent subsidy to help them purchase COBRA coverage.

As unemployment stubbornly hovers at 10 percent, we need to maintain these safety net programs. That is why I was glad to see

the President's request for an additional \$25.5 billion to extend the temporary FMAP increase, as well as another extension of the subsidy for COBRA continuation coverage. These immediate investments are critically important to making sure those families who continue to fall on hard times have the support they need from Washington.

This budget also plans for long-term investments in our health care system. For example, the efforts already underway and the investments the administration plans to make in the area of health information technology, or HIT, will help modernize our health care system, thereby improving the quality of care, improving efficiency, and lowering health care costs in the long run.

And Madam Secretary, this budget builds on a lot of our accomplishments from last year. That much is clear to me. But as you know, there is still a lot more to be done. We must rein in out-of-control health care costs that are choking America's working families, businesses, and the government. We need to improve access to affordable and quality health care coverage for the millions of Americans who are currently without health insurance or on the verge of losing the coverage that they currently have. And we need to put an end to the abuses and outright discrimination used by insurance companies to deny people the care they need and increase their profits.

In sum, we need a comprehensive health reform bill. And I look forward to working with you and the President on the many priorities laid out in this budget, especially enacting comprehensive health reform this year.

I thank you, Mr. Chairman, and also the Secretary for being here today, as always. Thank you.

Mr. WAXMAN. Thank you, Mr. Pallone.

The Chair recognizes Mr. Deal, the ranking member of the subcommittee.

Mr. DEAL. Mr. Chairman, I have 5 minutes; could I allocate time also among members?

Mr. WAXMAN. The gentleman is recognized for 5 minutes to use as he sees fit.

**OPENING STATEMENT OF HON. NATHAN DEAL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA**

Mr. DEAL. Thank you, Mr. Chairman.

This budget proposal, of course, leaves many unanswered questions; one, of course, is the question of the impact of the proposed health care reform legislation that is still pending. The budget, as I see it, leaves a placeholder with a projected savings of \$150 billion, but there are certainly questions relating to that. We know that the original proposal was to cut Medicare and help pay for the cost of any proposed new legislation. I would be interested to hear what the Secretary says with regard to the administration's position on that.

Also, the budget appears to write off almost \$400 billion in anticipation of the SGR fix. We obviously would be interested in knowing what is going to take the place of SGR and whether or not that new program would anticipate curbing over-utilization of Medicare services. But for many of us, Medicaid is one of the big-

gest areas of concern. Under this budget, the Federal share of Medicaid outlays would be \$297 billion for fiscal year 2011. That is a 7.8 percent increase over fiscal year 2010 and a \$95.4 billion, or a 47.4 percent increase, over fiscal year 2008 spending. That is of concern as we see the mandated expansion of Medicaid under the proposed bills that are now still pending. Those are concerns as to how the government—and States, of course, too—are going to be expected to pay for those expanded coverages.

I will yield at this time 1 minute to Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Deal. And Madam Secretary, welcome.

Today we are in the process of increasing the debt limit on the floor of the House. I think it is the fifth time that we have increased the debt limit since the Democrats have been in control of Congress, and we are doing so again.

Instead of freezing, can't we find one penny on the dollar savings across the board in Federal spending, just one cent of a dollar? I think we can, and that is why we have difficulty with this budget.

The discretionary end, as you know, is only about one-fourth of the budgetary spending. If we are not talking about the entitlement programs of Medicare and Medicaid, we are not addressing the real problems that we have in this catastrophic budget deficit and the debt that we are incurring. And as you know, on the entitlement programs of Medicaid, as they expand, which these health care plans do, we force the States to pay in more money that they don't have.

So we have a lot of questions, Mr. Chairman. I wish we had more time. I look forward to the rest of the questions that we have to offer, and I yield back.

Mr. DEAL. I yield to Mr. Murphy.

Mr. MURPHY of Pennsylvania. Thank you.

Madam Secretary, thank you for being here. Sometimes it is not a pleasant thing to be in front of Members of Congress. But I just thought I would make a recommendation of something that hopefully you will have some power or control of doing, and that is, as we look at health care issues, one of the things that I think is so important is looking at how we can save money, not deal with health care by raising taxes, not deal with health care by spending more, but sometimes look at our Medicare and Medicaid programs.

As you know, they were founded in the 1960s and have thousands of things they pay but—for none of us still drive a 1965 car—we hope not, unless it has been overhauled a few times. There are still incredible inefficiencies in those programs in things that unfortunately take an act of Congress to change, and things are not there yet in some programs. We should be doing more coordinating care.

The paperwork, the procedures, the prescription errors are still a problem for us. It takes months to get a motorized wheelchair. If someone gets some emergency medicine and they need more until a prescription arrives, the amount of paperwork physicians have to do, it just adds more to that.

Home infusion therapy is still not permitted even if someone is capable of doing that. That takes an act of Congress to change, too. So I hope that you will use your leadership and your position to

help streamline a lot of this. Quite frankly, I think we can save billions of dollars and tens of thousands of lives by making things better in this whole process. And there I think we will see an awful lot of savings which you can use to deal more with our health care in America.

With that, I yield back my time.

Mr. DEAL. I would be glad to yield to any other members on the Republican side who want time. If not, I yield back my time, Mr. Chairman.

Mr. WAXMAN. The gentleman yields back his time.

Mr. Dingell, do you wish to make an opening statement?

Mr. DINGELL. Mr. Chairman, thank you. I would like to welcome the Secretary to the committee. Her father, as we all remember, was a distinguished member of this committee and this body, and her father-in-law was a distinguished Republican Member of the Congress. Welcome.

In the interest of time, and out of my respect for my colleagues, I ask unanimous consent to insert my statement in the record.

[The prepared statement of Mr. Dingell follows:]

**Statement of  
The Honorable John D. Dingell  
Committee on Energy and Commerce Hearing  
“President’s Fiscal Year 2011 Budget for the Department of  
Health and Human Services”**

**February 4, 2010**

Thank you, Mr. Chairman. Madam Secretary, it is an honor to have you here today. I look forward to your testimony.

The budget that you are presenting to us today is a responsible document that recognizes the challenges of the recession while also making fiscal responsibility a key priority. Your commitment to reducing waste, fraud and abuse in the health care system is to be commended. The American taxpayers deserve to know how their dollars are being spent and should have full confidence that no penny is going to people or organizations that are cheating the system.

I am particularly pleased to see health care reform in your budget and I am confident we will see success on this front this year. Our nation’s fiscal health depends on it.

If we are to truly get serious about the federal budget deficit, we must press ahead on comprehensive health care reform. Just today we learned that health care costs consumed 17.3 percent of the GDP last year. The Congressional Budget Office predicts that if we do nothing, health care costs will grow to 25 percent in 2025, 37 percent in 2050, and 49 percent in 2082. This projected path is unsustainable to the federal government, businesses, and American families.

We are closer to enacting comprehensive health care reform than ever before and we can not stop now.

The President’s budget shows a clear commitment to programs critical to our people during our tough economic times:

- 6-month extension of the Recovery Act FMAP funding;
- Improvements in the LIHEAP program;
- Increased funding for child care assistance programs;
- Expansion of Community Health Centers.

I also note the President's sound commitment to science, including an increase in NIH and comparative effectiveness funding, and additional funding for the FDA.

Ensuring that the Food and Drug Administration the authority and resources it needs to properly protect the American people has been a long priority of mine. I am thankful for your partnership on this issue during our deliberations on food safety. I look forward to working with you on legislation on medical product safety in the near future. My hope is to provide the necessary authorities and resources to take FDA regulation into the 21<sup>st</sup> century.

Thank you again. I yield back the balance of my time.

Mr. WAXMAN. Thank you, Mr. Dingell.

Madam Secretary, we are delighted you are here. We have been looking forward to hearing from you. We wish we had been able to hear from you earlier, but we are delighted to recognize you now and to have you make such statements as you wish to make to us about the budget matter.

**STATEMENT OF KATHLEEN SEBELIUS, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Secretary SEBELIUS. Thank you very much.

Chairman Waxman, Chairman Emeritus Dingell, Ranking Member Barton, Representative Pallone, Representative Deal, and members of the committee, thank you for inviting me here to discuss the 2011 budget for the Department of Health and Human Services.

We think the budget builds on the themes that the President laid out in his State of the Union, strengthening security and opportunity for America's working families, investing to build a foundation for future growth, and bringing in a level of accountability and transparency to government. It abides by the pledge to root out programs that are redundant and obsolete.

Under this budget, we seek to provide the health and human services that Americans depend on more effectively and more focused results. We will make necessary investments that our country has been putting off for years, including investments in fighting health care fraud, strengthening our public health infrastructure, and getting serious about prevention and wellness.

The budget is a major step toward a healthier, stronger America, and we think that this budget and comprehensive health reform will make families healthier, create jobs, and give them the security and stability they need.

We are firmly committed to health insurance reform, and as the President reaffirmed, we are always willing to listen to ideas and work with anyone who is interested in finding a comprehensive solution to the health care crisis. Reform is still the best way to help millions of Americans without health insurance and millions more who are underinsured or who have a preexisting condition.

It is still the best way to help Americans who are just a pink slip away from losing their insurance. The administration continues to reach out to Members of Congress, doctors, nurses, hospitals, and other key partners in this effort.

But the investments we are making in 2011 support the goals of reform, improving America's access to the high-quality health care they need. I look forward to discussing the importance of these reforms with you, but I want to give you just a brief overview of the budget priorities for this year and then look forward to the questions.

From day one, the President said we need to put science first, and that is really how our Department is run, it is reflected in the budget. Whether it is fighting a pandemic or protecting food safety or transforming the health care system with electronic medical records, the investments we are making are guided by some of the best scientific and medical experts in the world. We are also guided by a constant vigilance about using taxpayer dollars wisely.



At a time when so many American families are scraping together every last dollar to pay their medical bills, fraud, waste and abuse are unacceptable. That is why this budget contains an historic investment in cracking down on the health care fraudsters who steal from taxpayers, endanger patients, and jeopardize Medicaid and Medicare's future. The investment allows us to build on efforts that began last May when the President asked the Attorney General and me to put together a new fraud task force known as HEAT. It is an unprecedented partnership, bringing together high-level leaders from both departments to share information, spot trends, coordinate strategies, and develop new fraud, prevention and prosecution teams.

One year ago today, we extended access to millions of children through the CHIP Reauthorization Act. In 2009, we know that 2.5 million more children who were previously uninsured got health care coverage from Medicaid or CHIP. Now part of that landmark legislation contains funds to help us reach out to the approximately 4 to 5 million children who are eligible but not yet enrolled in those critical programs.

We are also investing new funds in what I consider to be the backbone of the American health care system, community health centers. Thanks to this investment, the neighborhood centers will provide high-quality primary care for 20 million people a year, 3 million more than were able to be served in 2008. The budget ensures up-to-date care for seniors and people with disabilities who depend on Medicare.

On top of that, we have almost \$1 billion in funding to strengthen and support our country's health care workforce. We increase funds for the Indian health service. American Indians and Alaska Natives historically have not gotten the care they have been promised and deserve, but we are working to change this because, regardless of race, ethnicity, gender, disability or geography, every American deserves high-quality, affordable care.

We are investing in next-generation health care technologies to help providers raise the quality of care for all Americans. The adoption by doctors and hospitals of electronic health records reduces medical errors, helps coordinate care, and cuts cost and paperwork.

This budget does assume a zero percent update for physician payments. Everyone agrees that the scheduled Medicare physician payment cuts are not sustainable and would seriously damage access to care for Medicare beneficiaries. So we are recognizing this as an honest budget that reflects Congress' continued action in this area. And we look forward to working with you, Mr. Chairman, and your committee to develop the payment policy to give physicians incentives to improve quality and efficiency.

Our budget is based on our growing understanding that health is influenced by many factors outside a doctor's office. Where you live matters, what you eat and drink matters, even what you watch on television. And to help more Americans live healthy lifestyles, the budget continues the work of rebuilding the public health infrastructure. What we have today is overwhelmingly a sick care system, where we wait until something goes wrong to intervene. We are trying to build a true health care system. To that end, the

budget creates a new program at the Centers for Disease Control and Prevention that will work to reduce the rates of disability and morbidity due to chronic disease in 10 of our biggest U.S. cities. It will allow us to begin the serious fight against obesity, a problem costing our health care system almost \$150 billion a year.

There is a significant increase to help us build a 21st century food safety system to go along with our 21st century food market where nearly half our fruit and over three-quarters of our seafood come from overseas. We are expanding the efforts of the new Food Safety Working Group that I cochair with Agriculture Secretary Tom Vilsack. The additional funding allows us to update food safety standards, enhance surveillance and response, and hire 350 additional food inspectors. It makes a serious investment in our battle against smoking. The budget provides significant funds for educating children about the dangers of smoking and new research to help us develop better ways to stop Americans from smoking.

While we continue to do the steady work of promoting health care, we also need to prepare for public health emergencies, whether their cause is mother nature or our fellow man. Some of the best defenses are medical countermeasures—vaccines, treatments, respirators, among other things, that help reduce the spread of infections, reduce health consequences, and ultimately save lives.

This flu season we got a wake-up call about the readiness of our countermeasures. Even as our scientists and private sector partners scrambled to produce a safe, effective vaccine in six months—three months faster than it usually takes—we saw temporary vaccine shortages because the vaccine grew slowly in chicken eggs, an unpredictable process we have used for the last 50 years. So the budget includes a half billion dollars to upgrade countermeasures. Just as important, it contains significant funds for NIH for research that continues many of the breakthroughs that make these countermeasures possible.

We are also taking a comprehensive review of our entire countermeasure production process, from laboratory to the doctor's office, and we will have a report to give this committee later this year.

Strengthening America's health is half of our mission, and our budget goes a long way to restoring health security for Americans, but the other half of the mission is providing security and opportunity for America's working families. Middle class families aren't just taking care of their children these days—and we have provided some additional help with child care—but they are also often dealing with aging parents. Eighty percent of the long-term care services in this country are provided by family members; great for older Americans to be cared for by their loved ones, but often financially and physically exhausting for caregivers. So there is significant new support for those family caregivers, including counseling and information about how to best care for elders, adult day care centers to help drop parents off for a day, and transportation to get seniors to the doctor or the grocery store. Investments help give caregivers relief and help them keep their loved ones at home as long as possible.

And finally, the budget extends relief that we provided last year for States and communities facing budget cuts across this country,

helping States maintain essential supports and services at a time when working Americans need them most.

There is no question that hardworking people of this country have been tested over the last few years. As President Obama said in his State of the Union, we urge Americans to rise to the challenges posed by our current difficulties and pledge that as a country we will face these challenges together.

We are closer than ever to passing health reform, and we intend to work with you to finish the job for the American people. The 2011 budget will support an enhanced reform, making long-overdue investments in strengthening our health care and public health systems, keeping all of us healthy and more secure while targeting relief directly to working Americans who need it most. My department clearly can't accomplish any of these goals alone, it will require all of us working together.

Thank you, and I look forward to your questions.

[The prepared statement of Secretary Sebelius follows:]



**STATEMENT OF**  
**KATHLEEN SEBELIUS**  
**SECRETARY**  
**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**ON**

**THE PRESIDENT'S FISCAL YEAR 2011 BUDGET**

**BEFORE THE**  
**COMMITTEE ON ENERGY AND COMMERCE**  
**UNITED STATES HOUSE OF REPRESENTATIVES**

**FEBRUARY 4, 2010**

Chairman Waxman, Chairman Emeritus Dingell, Ranking Member Barton, Representative Pallone, Representative Deal and Members of the Committee, thank you for the invitation to discuss the President's FY 2011 Budget for the Department of Health and Human Services (HHS).

Last week, in his State of the Union, President Obama laid out an aggressive agenda to create jobs, strengthen opportunity for working families, and lay a foundation for long-term growth. His fiscal year (FY) 2011 budget is the blueprint for putting that vision into action.

At HHS, we are supporting that agenda by working to keep Americans healthy, ensure they get the health care they need, and provide children, families, and seniors with the essential human services they depend on.

Our budget will make sure that the critical health and human services our Department offers to the American people are of the highest quality and are directly helping families stay healthy, safe, and secure—especially as we continue to climb out of a recession.

It promotes projects that will rebuild our economy by investing in next generation research and the advanced development of technology that will help us find cures for diseases, innovative new treatments, and new ways to keep Americans safe, whether we are facing a pandemic or a potential terrorist attack.

But this budget isn't just about new programs or new priorities or new research. It is also about a new way of doing business with the taxpayers' money. Where there is waste and fraud, we must root it out. Where there are loopholes, we must close them. And where we have opportunities to increase transparency, accountability, and program integrity, we must take them. These are top priorities of the President. They are top priorities of mine. And our budget will make them top priorities for my department as well.

The President's FY 2011 Budget for HHS totals \$911 billion in outlays, 90 percent of which is within the jurisdiction of the Committee on Energy and Commerce.

### ***Reducing Health Care Fraud***

When American families are struggling to make every dollar count, we need to be just as vigilant about how their money is spent. That's why the Obama Administration is cracking down on criminals who steal from taxpayers, endanger patients, and jeopardize the future of our government health insurance programs.

Last May, President Obama instructed Attorney General Holder and me to create a new Health Care Fraud Prevention and Action Team, which we call HEAT for short. HEAT is an unprecedented partnership that brings together high-level leaders from both

departments so that we can share information, spot trends, coordinate strategy, and develop new fraud prevention tools.

As part of this new partnership, we are developing tools that will allow us to identify criminal activity by analyzing suspicious patterns in claims data. Medicare claims data used to be scattered among several databases belonging to different contractors. If we wanted to find out how many claims had been made for a certain kind of wheelchair, we had to go look in several different places. But now, we are combining all Medicare paid claims data into a single, searchable database. Which means that for the first time ever, we'll have a complete picture of what kinds of claims are being filed across the country and where they're being filed from.

Our FY 2011 Budget includes \$1.7 billion in funding to fight fraud, including \$561 million in discretionary funds, to strengthen these Medicare and Medicaid program integrity activities, with a particular emphasis on fighting health care fraud in the field, increasing Medicare and Medicaid audits, and strengthening program oversight while reducing costs.

This investment, will better equip the Federal government to minimize inappropriate payments, pinpoint potential weaknesses in program integrity oversight, target emerging fraud schemes by provider and type of service, and establish safeguards to correct programmatic vulnerabilities. This multi-year discretionary investment will save \$9.9 billion over ten years.

The Budget also includes a set of new administrative and legislative program integrity proposals that will give HHS the necessary tools to fight fraud by enhancing provider enrollment scrutiny, increasing claims oversight and improving Medicare's data analysis capabilities and will save approximately \$14.7 billion over ten years.

#### ***Improving Quality of and Access to Health Care***

At HHS, we continue to find ways to better serve the American public, especially those citizens least able to help themselves. We are working to improve the quality of and access to health care for all Americans by supporting programs intended to enhance the health care workforce and the quality of health care information and treatments through the advancement of health information technology (IT) and the modernization of the health care system.

As Congress continues its work to provide security and stability for Americans with health insurance and expand coverage to those Americans who do not have insurance, HHS maintains its efforts towards achieving those goals through activities with the Children's Health Insurance Program (CHIP), health IT, patient-centered health research, prevention and wellness, community health centers, and the health workforce.

Additional resources distributed to States and Territories after the enactment of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) resulted in 19 States expanding or improving child health coverage in FY 2009. Forty-seven States

now cover children in families with incomes at or above 200 percent of the Federal poverty guidelines. In September of 2009, CMS awarded \$40 million in grants to assist in enrolling the over 5 million children who are uninsured but eligible for either Medicaid or CHIP.

The Budget includes \$3.6 billion to strengthen the ability of the Centers for Medicare & Medicaid Services (CMS) to meet current administrative workload demands resulting from recent legislative requirements and continued beneficiary growth. The funding provides targeted investments to revamp IT systems and optimize staffing levels so that CMS can meet the future challenges of Medicare and Medicaid while being an active purchaser of high quality and efficient care.

For example, \$110 million will support a comprehensive Health Care Data Improvement Initiative to transform CMS's data environment from one focused primarily on claims processing to one also focused on state-of-the art data analysis and information sharing. These changes are vital to modernizing the Medicare and Medicaid programs by making CMS a leader in value-based purchasing, improving systems security, and increasing analytic capabilities and data sharing with key stakeholders.

Everyone agrees that the scheduled Medicare physician payment cuts are not sustainable and would likely impact access to care for our Medicare beneficiaries. We look forward to working with Congress to reform Medicare's payment policy and give physicians incentives to improve quality and efficiency. The Budget assumes a zero percent update for physician payments. This is not a proposed policy but an honest and transparent budget display reflecting the Administration's best estimate of future Congressional action based on what Congress has done in recent years for physician payments.

The Budget includes \$995 million for the Health Resources and Services Administration (HRSA) for a wide range of programs to strengthen and support our Nation's health care workforce. This funding will enhance the capacity of nursing schools, increase access to oral health care through dental workforce development grants, target minority and low income students, and place an increased emphasis on ensuring that America's senior population gets the care and treatment it needs.

The Budget includes an increase of \$290 million to ensure better access to health centers through further expansions of health center services and integration of behavioral health into health centers' primary care system. This funding builds on investments made under the American Recovery and Reinvestment Act (Recovery Act) of 2009 and will enable health centers to serve more than 20 million patients in FY 2011, which is more than 3 million patients than were served in FY 2008.

The President is committed to improving health outcomes and reducing health disparities for American Indian and Alaska Native communities. The Budget includes nearly \$5.4 billion in budget authority and collections, an increase of \$354 million, enabling the Indian Health Service (IHS) to focus on reducing health disparities, supporting Tribal efforts to deliver high-quality care, ensuring that IHS services can be supplemented by

care purchased outside the Indian health system where necessary, and funding health facility and medical equipment upgrades.

The Budget advances the President's health IT initiative by accelerating health IT adoption and electronic health records (EHRs) utilization – essential tools for modernizing the health care system. The Budget includes \$78 million, an increase of \$17 million, for the Office of the National Coordinator for Health Information Technology (ONC) to continue its current efforts as the Federal health IT leader and coordinator. During FY 2011, HHS will also begin providing an estimated \$25 billion over 10 years of Recovery Act Medicare and Medicaid incentive payments to physicians and hospitals who demonstrate meaningful use of certified EHRs, which will improve the reporting of clinical quality measures and promote health care quality, efficiency, and patient safety.

To continue to fulfill the President's commitment to ensuring access to health care for millions of Americans, the Budget includes a proposal to extend by an additional six months, through June 2011, the temporary Federal Medical Assistance Percentage (FMAP) increase provided by the Recovery Act. The extension will result in an additional \$25.5 billion to States and Territories for maintaining support for children and families helped by Medicaid and promoting economic recovery by helping State budgets.

The Budget supports HHS-wide patient-centered health research, including \$286 million within the Agency for Healthcare Research and Quality (AHRQ). HHS also continues to invest the \$1.1 billion provided by the Recovery Act to improve health care quality by providing patients and physicians with state-of-the-art, evidence-based information to enhance medical decision-making.

#### ***Promoting Public Health***

Whether responding to pandemic flu or preventing food-borne illness, HHS will continue its unwavering commitment to keeping Americans healthy and safe.

The President is committed to securing our Nation's food supply by transforming and improving our food safety system. The Budget includes \$1.4 billion, an increase of \$327 million, for food safety efforts that will strengthen the ability of the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to prioritize prevention, strengthen surveillance and enforcement, and improve response and recovery – key priorities of the Food Safety Working Group the President established in March 2009.

In June 2009, the President signed the Family Smoking Prevention and Control Act, providing FDA with new authorities and responsibilities for regulating tobacco use and establishing the FDA Center for Tobacco Products. The Budget includes \$450 million from user fees to reduce tobacco use in minors by regulating marketing and distribution of tobacco products, promote public health understanding of harmful constituents of tobacco products, and reduce the toll of tobacco-related disease, disability, and mortality. In addition, \$504 million in funding for CDC, the National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA) will



further help reduce smoking among teens and adults and will support research on preventing tobacco use, understanding the basic science of the consequences of tobacco use, and improving treatments for tobacco-related illnesses.

The Budget includes over \$3 billion, an increase of \$70 million, for CDC and HRSA to enhance HIV/AIDS prevention, care, and treatment. This increase includes \$31 million for CDC to integrate surveillance and monitoring systems, address high-risk populations, and support HIV/AIDS coordination and service integration with other infectious diseases. It also includes \$40 million for HRSA's Ryan White program to expand access to care for underserved populations, provide life-saving drugs, and improve the quality of life for people living with HIV/AIDS.

Reducing the burden of chronic disease, collecting and using health data to inform decision-making and research, and building an interdisciplinary public health workforce are critical components to successful prevention efforts. The Budget includes \$20 million for a CDC initiative to reduce the rates of morbidity and disability due to chronic disease in up to ten of the largest U.S. cities. These cities will be able to incorporate the lessons learned from implementing evidence-based prevention and wellness strategies of the Recovery Act's Communities Putting Prevention to Work Initiative.

The Budget also includes \$10 million at CDC for a new Health Prevention Corps, which will recruit, train, and assign a cadre of public health professionals in State and local health departments. This program will target disciplines with known shortages, such as epidemiology, environmental health, and laboratory science.

To improve CDC's ability to collect data on the health of the Nation for use by policy-makers and Federal, State, and local leaders, the Budget provides \$162 million for Health Statistics, an increase of \$23 million above FY 2010. This increase will ensure data availability on key national health indicators by supporting electronic birth and death records in States and enhancing national surveys.

There is \$222 million, an increase of \$16 million, included in the Budget to address Autism Spectrum Disorders (ASD). NIH research will pursue comprehensive and innovative approaches to defining the genetic and environmental factors that contribute to ASD, investigate epigenetic changes in the brain, and accelerate clinical trials of novel pharmacological and behavioral interventions. CDC will expand autism monitoring and surveillance and support an autism awareness campaign. HRSA will increase resources to support children and families affected by ASD through screening programs and evidence-based interventions.

To support teen and unintended pregnancy prevention activities in the Office of Public Health and Science and CDC, the Budget provides \$205 million in funds.

To invest in innovative approaches to prevent and treat substance abuse through evidence-based community prevention programs, a warning system to detect emerging

drug threats, and the expansion of drug courts capacity, the Budget includes \$93 million within SAMHSA.

The Budget includes \$352 million, an increase of \$16 million, for CDC Global Health Programs to build global public health capacity by strengthening the global public health workforce; integrating maternal, newborn, and child health programs; and improving global access to clean water, sanitation, and hygiene. Additionally, the Budget includes \$6.4 million in the Office of Global Health Affairs to support global health policy leadership and coordination.

Finally, for FDA's medical product safety initiative to increase inspections and invest in tools that will enhance the safety of increasingly complex drugs, medical devices, and biological products, the Budget provides \$1.4 billion, an increase of \$101 million above the FY 2010 funding level.

***Protecting Americans from Public Health Threats and Terrorism***

Continued investments in countermeasure development and pandemic preparedness will help ensure HHS's preparedness to protect the American people in natural or man-made public health emergencies.

The Budget includes \$476 million, an increase of \$136 million, for the Biomedical Advanced Research and Development Authority to sustain the support of next generation countermeasure development in high priority areas by allowing the BioShield Special Reserve Fund to support both procurement activities and advanced research and development.

Reassortment of avian, swine, and human influenza viruses has led to the emergence of a new strain of H1N1 influenza A virus, 2009 H1N1 flu, that is transmissible among humans. On June 24, 2009, Congress appropriated \$7.65 billion to HHS for pandemic influenza preparedness and response to 2009 H1N1 flu. HHS has used these resources to support H1N1 preparedness and response in States and hospitals, to invest in the H1N1 vaccine production, and to conduct domestic and international response activities. The Budget includes \$302 million for ongoing pandemic influenza preparedness activities at CDC, NIH, FDA, and the Office of the Secretary for international activities, virus detection, communications, and research. In addition, the use of balances from the June 2009 funds, including approximately \$330 million in FY 2011, will enable HHS to continue advanced development of cell-based and recombinant vaccines, antivirals, respirators, and other activities that will help ensure the Nation's preparedness for future pandemics.

***Improving the Wellbeing of Children, Seniors, and Households***

In addition to supporting efforts to increase our security in case of an emergency, the HHS Budget also seeks to increase economic security for families and open up doors of opportunity to those Americans who need it most.

The Budget provides critical support of the President's Zero to Five Plan to enhance quality early care and education for our Nation's children. The Budget lays the groundwork for a reauthorization of the Child Care and Development Block Grant and entitlement funding for child care, including a total of \$6.6 billion for the Child Care and Development Fund (discretionary and entitlement child care assistance), an increase of \$1.6 billion. These resources will enable 1.6 million children to receive child care assistance in FY 2011, approximately 235,000 more than could be served in the absence of these additional funds.

The Administration's principles for reform of the Child Care and Development Fund include establishing a high standard of quality across child care settings, expanding professional development opportunities for the child care workforce, and promoting coordination across the spectrum of early childhood education programs. The Administration looks forward to working with Congress to begin crafting a reauthorization proposal that will make needed reforms to ensure that children receive high quality care that meets the diverse needs of families and fosters healthy child development.

To enable families to better care for their aging relatives and support seniors trying to remain independent in their communities, the Budget provides \$102.5 million for a new Caregiver Initiative at the Administration on Aging. This funding includes \$50 million for caregiver services, such as counseling, training, and respite care for the families of elderly individuals; \$50 million for supportive services, such as transportation, homemaker assistance, adult day care, and personal care assistance for elderly individuals and their families; and \$2.5 million for respite care for family members of people of all ages with special needs. This funding will support 755,000 caregivers with 12 million hours of respite care and more than 186,000 caregivers with counseling, peer support groups, and training.

The Head Start program, run by the Administration for Children and Families (ACF), will serve an estimated 971,000 children, an increase of approximately 66,500 children over FY 2008. Early Head Start will serve approximately 116,000 infants and toddlers, nearly twice as many as were served in FY 2008. The Budget includes an additional \$989 million for Head Start to sustain and build on these historic increases enabled by Recovery Act investments. The increase includes \$118 million in funds to improve program quality, and the Administration plans to implement key provisions of the 2007 Head Start Act reauthorization related to grantee recompetition, program performance standards, and technical assistance that will improve the quality of services provided to Head Start children and families.

To continue to fulfill the President's commitment to improving the development, safety, well-being, and permanency of children and youth in foster care, adoption assistance, and guardianship assistance, the Budget includes a proposal to extend by an additional six months, through June 2011, the temporary FMAP increase for foster care and adoption assistance provided by the Recovery Act. This extension will result in an

additional \$237 million to States for maintaining critical services to vulnerable children and youth.

The Budget includes an extension of the Temporary Assistance for Needy Families (TANF) block grant and related programs, including the Contingency Fund and Supplemental Grants, through FY 2011. The Budget also incorporates the Healthy Marriage and Responsible Fatherhood grant funding into a new \$500 million Fatherhood, Marriage, and Families Innovation Fund. The fund will provide competitive grants to States to conduct and rigorously evaluate comprehensive responsible fatherhood programs and new demonstrations geared towards improving child outcomes by improving outcomes for custodial parents with serious barriers to self-sufficiency. Because the TANF Emergency Fund helps States to create subsidized jobs for unemployed low-income individuals, the Budget also includes an additional \$2.5 billion for the TANF Emergency Fund and makes several changes to facilitate State efforts to create jobs and provide work supports for needy families.

The Budget includes a one-year, \$669 million extension of the Federal match to States' reinvestment of incentive payments into Child Support Enforcement programs. Without this critical extension of resources, it is estimated that States would reduce program expenditures by 10 percent. The Budget also includes two proposals focused on increasing child support collections and a proposal to expand resources for non-custodial parents' access to and visitation with their children.

The Budget proposes a new way to fund the Low Income Home Energy Assistance Program (LIHEAP) to help low-income households heat and cool their homes. Our request provides \$3.3 billion in discretionary funding. The proposed new trigger would provide under our current estimates \$2 billion in mandatory funding. Energy prices are volatile, making it difficult to match funding to the needs of low-income families, so under this proposal, mandatory funds will be automatically released in response to quarterly spikes in energy prices or annual changes in the number of people living in poverty. The \$2 billion estimate is based on current projections of Supplemental Nutrition Assistance Program usage and energy prices.

#### ***Investing in Scientific Research and Development***

The investments that HHS is proposing in our human services budget will expand economic opportunity but another critical way to grow and transform our economy is through a healthy investment in research that will not only save lives but also create jobs.

The Budget includes a program level of \$32.2 billion for NIH, an increase of \$1 billion, to support innovative projects from basic to clinical research. This effort will be guided by NIH's five areas of exceptional research opportunities: supporting genomics and other high-throughput technologies; translating basic science into new and better treatments; reinvigorating the biomedical research community; using science to enable health care reform; and focusing on global health. The Administration interest for the high-priority areas of cancer and autism fits well into these five NIH theme areas. In FY 2011, NIH

estimates it will support a total of 37,001 research project grants, including 9,052 new and competing awards.

The additional \$1 billion will enable NIH to capitalize upon recent successful investments in biomedical research, such as the Human Genome Project, that have provided a powerful foundation for a deeper level of understanding human biology and have opened another window into the causes of disease. New partnerships between academia and industry are working to revitalize the drug development pipeline. An era of personalized medicine is emerging where prevention, diagnosis, and treatment of disease can be tailored to an individual rather than using the one-size-fits-all approach that all too often falls short, wasting health care resources and potentially subjecting patients to unnecessary and dangerous medical treatments and diagnostic procedures.

To advance regulatory science at FDA, the Budget provides \$25 million. This initiative builds on the President's commitment to harness the power of science for America's benefit and includes \$15 million for nanotechnology related research, which holds great promise for advances in medical products and cosmetics. The additional resources will also enable FDA to update review standards and provide regulatory pathways for new technologies, such as biosimilars.

#### ***Recovery Act***

Since the Recovery Act was passed in February 2009, HHS has made great strides in improving access to health and social services, stimulating job creation, and investing in the future of health care reform through advances in health IT, prevention, and scientific research. HHS Recovery Act funds have had an immediate impact on the lives of individuals and communities across the country affected by the economic crisis and the loss of jobs.

As of September 30, 2009, the \$31.5 billion in Federal Payments to States helped maintain State Medicaid services to a growing number of beneficiaries and provided fiscal relief to States. The National Institutes of Health awarded \$5 billion for biomedical research in over 12,000 grants. Area agencies on aging provided more than 350,000 seniors with over 6 million meals delivered at home and in community settings. Health Centers provided primary health care services to over one million new patients.

These programs and activities will continue in FY 2010, as more come on line. For example, 64,000 additional children and their families will participate in a Head Start or Early Head Start experience. Approximately 30,000 American Indian and Alaska Natives' homes will have safe drinking water and adequate waste disposal facilities. HHS will be assisting States and communities to develop capacity, technical assistance and a trained workforce to support the rapid adoption of health IT by hospitals and clinicians. The CDC will support community efforts to reduce the incidence of obesity and tobacco use. New research grants will be awarded to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers about what interventions are most effective for patients under specific circumstances.

The Recovery Act provides HHS programs an estimated \$141 billion for Fiscal Years 2009 – 2019. While most provisions in HHS programs involve rapid investments, the Recovery Act also includes longer term investments in health IT (primarily through Medicare and Medicaid). As a result, HHS plans to have outlays totaling \$87 billion through FY 2010.

***Conclusion***

This testimony reflects just some of the ways that HHS programs improve the everyday lives of Americans. Under this budget, we will provide greater security for working families as we continue to recover from the worst recession in 70 years.

We will invest in research on breakthrough solutions for healthcare that will save money, improve the quality of care, and energize our economy. And we will push forward our goal of making government more open and accountable.

My department cannot accomplish any of these goals alone. It will require all of us to work together. And I look forward to working with you to advance the health, safety, and well-being of the American people. Thank you for this opportunity to speak with you today. I look forward to answering your questions.

Mr. WAXMAN. Thank you very much, Madam Secretary. That was an excellent review of the budget.

I want to start off the questions. First of all, I want to say how pleased I am with the President's continued commitment to health care reform. It is a goal that we share. I know that you have done a lot of thinking about how to make sure that we are ready for reform and that your budget reflects critical building blocks in that effort. Members of this committee have been particularly concerned to make reform work, and we need to ensure access through more health centers and training of health professionals, and to take advantage of new health information technologies, and to recommit to prevention and public health.

I want to ask you some specific questions, however, about Medicare. There are two critical priority areas I see in this particular area. First, we need to improve Medicare coverage of prescription drug costs by filling in the donut hole in the drug benefit. Seniors should not have to go without needed medicines due to lack of coverage. And second, beneficiaries must be able to get the care they need from their physicians, and that requires fair and predictable payment. So we must permanently reform the broken physician payment system in Medicare.

Could you elaborate on the administration's policies in these two areas?

Secretary SEBELIUS. Certainly, Mr. Chairman.

I think that the donut hole, the reduction of the excess costs that too many seniors have to pay when they reach their limits in the prescription drug program are parts of both the House and Senate plans on health reform. They are not repeated in this budget; we are assuming that we will move ahead on health reform and have those as part of the critical future. But as you know, it is one of the most serious issues for seniors across this country, and way too many people hit that gap and don't have the wherewithal to pay 100 percent out of pocket for the drugs that keep them out of the hospital and keep them well.

The most serious challenge facing Medicare beneficiaries right now is the 21 percent scheduled budget cut to their doctors. I talk to doctors every day, I talk to seniors every day, and they tell me that that isn't possible that we would have a system guaranteeing health care for seniors and cutting those payments. Our budget assumes that over the next 10 years, we will not cut those payments 21 percent. We look forward to working with you, Mr. Chairman, to find a specific policy—as you know, both the House and the Senate have addressed this plan in the past.

We look forward to both the House and Senate addressing it, but it is a problem looming, facing the 43 million Americans who depend on Medicare benefits. If that kind of cut were to occur, we would not have providers to deliver those essential services.

Mr. WAXMAN. Well, I am pleased that you are committed, as we are, to deal with both of those issues, and we have to find a way to do it.

I want to ask you a question about Medicaid. When unemployment goes up, families lose their incomes and their health insurance, so the need for Medicaid increases. At the same time, State revenues necessary to pay for Medicaid decline. To help States

maintain their Medicaid programs during the recession, the Recovery Act we enacted last year included a temporary increase in the Federal Medicaid Matching Payments, or FMAP. Each State received at least a 6.2 percent increase, and States with very high unemployment received more. This temporary FMAP increase will expire at the end of December. Unfortunately, many States are still expecting high unemployment and sharp declines in revenues well into 2011. The President's budget recognizes this problem and requests an extension of the FMAP increase through June 2011. The House has twice passed such a 6-month extension, once in the health reform bill and once in the jobs bill.

My question for you, Madam Secretary, is, what happens next January if we fail to extend this FMAP increase? What are the implications for State budgets, for health care providers, for health care workers, for Medicaid beneficiaries?

Secretary SEBELIUS. Well, Mr. Chairman, as you know, I came to this Cabinet position directly from a governorship in the State of Kansas, where I served until the very end of April last year. So I was a governor cutting the very budgets you talk about. And I can tell you from my personal experience how the stimulus package, the Recovery Act funds, not only helped us to make sure that we did not have to slash essential benefits at a time when additional Kansans needed those benefits, but, in fact, saved jobs.

State budgets are largely education funding and health care funding. Those are often somewhere between 75 and 90 percent of the budget. If we did not have those additional resources to help keep health services, in fact, we would have laid off teachers, we would have laid off correctional officers, highway patrol, jobs all over because there is no place else to get that money.

So not only is it an essential service, but I think it is directly related to thousands of jobs in my State and hundreds of thousands, perhaps millions of jobs around the country.

Every governor in this country—and I talk to my former colleagues on a regular basis—describe this as one of their top priorities, the continuation of the FMAP assistance through June of next year, which is the State fiscal year. This will get most States through their next fiscal year. I think it is absolutely an essential part of our recovery moving forward. Absent that, the modest progress now being made in States that they hope will be more significant progress over the next several months, focusing on jobs, on new development, on innovation will take a major step back.

Mr. WAXMAN. Thank you very much.

Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman. Thank you, Madam Secretary, for being here.

Before I ask questions, let me just compliment you on one part of our budget, or the President's budget. The budget for the community health centers was increased by \$290 million. That is something that I think most Republicans support; I know I do. The community health centers in my district do excellent work and they do it very efficiently. So I want to be positive about that, and I am sure that you are very supportive of that, too.

Back in September, myself and Congressman Walden, the ranking member of the Oversight Subcommittee, sent you a letter about



the use of title 42 funding. Title 42 gives the Health and Human Services Department the ability to pay certain of its employees above the general schedule to attract the very top talented NIH in certain research situations. This title 42 authority is explicitly limited to Health and Human Services. In the last 10 years, over 3,000 employees have been given this designation by HHS, some of them make well over \$300,000 a year. That, in and of itself, is not necessarily a bad thing. I think it is something we need to look at in the terms of tight budget authority.

But my question today and the question in the letter, the Environmental Protection Agency is now using title 42 authority. And my question to you first is, is the EPA now part of Health and Human Services?

Secretary SEBELIUS. Not to my knowledge.

Mr. BARTON. Is the Surgeon General an employee or a part of Health and Human Services?

Secretary SEBELIUS. Yes, sir. The Surgeon General has always—I don't know always, but certainly is a part of our Department under the Office of Public Health and Science.

Mr. BARTON. Could you construe the administrator at EPA to be the Surgeon General?

Secretary SEBELIUS. No, sir. We have a Surgeon General, Regina Benjamin is the Surgeon General of the United States.

Mr. BARTON. OK. Then why in the world do you allow the Environmental Protection Agency to use title 42 authority—which is explicit to your Department—to create a program at EPA to put their employees in the special designation by the hundreds of people? Are you aware that that is happening?

Secretary SEBELIUS. Sir, I am aware of your letter, and I have had some discussions with the staff. We are trying to get the most complete answer we can. But as far as I know, there has been no explicit or implicit designation of authority to the Environmental Protection Agency.

Mr. BARTON. Well, you just gave more information in the last 30 seconds than we have gotten in the last six months.

Secretary SEBELIUS. Well, as I say, series of events, I was not here. I don't know when this practice started. We are working on your letter. We want to get you a thorough and complete answer. I am telling you what I know at this point, but we will fully answer your letter and I intend to.

Mr. BARTON. Well, I have another copy of the letter; I am more than willing to give it to you again.

We have a situation where the Environmental Protection Agency appears to be completely without authority to set up a program. They even have a manual, apparently, at the EPA on how to convert their employees to title 42 employees. Now, you just said, rightfully so—and I commend you for being honest—that the Environmental Protection Agency is not a part of HHS, and the EPA administrator can in no way be construed to be the Surgeon General.

So you understand the law. My request is that you now enforce the law with the EPA and answer the letter—which we sent copies to Mr. Waxman and Mr. Stupak, Mr. Walden and I—so we can stop this practice. I mean, do you agree with me that the EPA

should not be setting up a title 42 program since title 42 is explicitly designed to give some additional financial encouragement and compensation to our highest scientists and researchers at NIH and FDA?

Secretary SEBELIUS. Mr. Barton, what I can assure you is that I will thoroughly investigate this and I will get you a complete answer to your letter as promptly as we possibly can.

Mr. WAXMAN. The gentleman's time has expired.

Mr. Pallone.

Mr. PALLONE. Thank you, Mr. Chairman.

Madam Secretary, I mentioned in my opening statement, I think I mentioned both the FMAP increase and the COBRA subsidy have been critical in helping Americans who have been hard hit by the recession. Chairman Waxman already asked you about extending the FMAP increase, which I support, but I wanted to also ask you about extending the COBRA subsidy. And essentially what would be the impact if we didn't make this COBRA subsidy expansion, not looking for numbers, but just generally why that is important and what would happen if we didn't do it?

Secretary SEBELIUS. Well, Congressman Pallone, I think that, as you well know, COBRA is an effective tool, but often not financially viable for way too many folks, particularly folks who have lost their jobs in a downturn. The opportunity to purchase 100 percent of their previous coverage is a nice offer, but often out of reach. So what this bridge program allows is, with some additional help from the Federal Government, workers who are laid off and their families can continue to have essential health services. Again, absent health reform, which could create an alternate, more viable, more affordable market, this is an essential way to make sure that hard-working families who have lost their job through no fault of their own continue to have health services.

Mr. PALLONE. Well, let me say I do hear from a lot of these people because, as you know, before they made the current extension there were a lot of people that were in danger, or actually already had—I think there was a week or so there when some actually had lost their subsidy, and many of them did call my office and said they wouldn't be able to continue their coverage. Do we have any idea the numbers that might not be able to make that 100 percent without the subsidy? Do we have any idea? Maybe can you get back to me on that.

Secretary SEBELIUS. I would be glad to. I think it is likely, though, a laid off worker is almost guaranteed not to be able, unless they have a huge nest egg, to be able to pay out of pocket for 100 percent of the previously covered employer costs.

Mr. PALLONE. So you think it is actually—maybe not 100 percent, but very close to it.

Secretary SEBELIUS. That was certainly, again, not only my personal experience talking to me, but what I saw across the country. They are scrambling to pay rent, buy food, and unfortunately health insurance is often something that has to go by the boards. As desperately as they would like to continue it, it just isn't a viable option.

Mr. PALLONE. Thank you.

Let me ask you about SCHIP also. Today literally marks the 1 year anniversary since the President signed into law the CHIPRA program, which is a variation on SCHIP that we passed in the last year or so. I am particularly proud of that legislation because we worked in a bipartisan fashion to increase access for, I think, about 11 million children.

Can you tell me how implementation of CHIPRA has gone over the past year; how has insurance coverage and the quality of the coverage improved for kids; and how have you been working with the States to increase coverage and improve retention rates?

Secretary SEBELIUS. Well, what I am pleased to report, Congressman Pallone, is that, in spite of the downturn in the budget of most States across the country, State leaders are seeing ensuring our children a fundamental piece of making sure we have a healthy, prosperous future. So States are actually increasing coverage for children. Many States have actually increased the threshold of the poverty level for whom the CHIP program applies.

Congress, I think wisely, provided some outreach funds. So we have put those funds in the hands of State leaders and State partners to actually try and enroll kids. It is one thing to have them eligible, it is another thing to find and enroll children. Those partnerships are very creative and underway with faith-based communities and medical outreach centers with community health centers. I just did an event today with Secretary Vilsack looking at the opportunity to try and make sure that enrollment is as easy as possible, and as a family is signing up for the supplemental nutrition program, they also can sign up their children for health insurance. And what we know is that about 2.5 million additional children in the year since CHIPRA has been extended have been signed up and enrolled, again, in spite of very difficult budget times, and I think that is good news.

Mr. PALLONE. That is very good news. And I thank you for all your efforts. And those outreach programs I think are particularly important.

Thank you.

Mr. WAXMAN. The gentleman's time has expired.

Mr. Blunt.

Mr. BLUNT. Thank you, Mr. Chairman.

Madam Secretary, thanks for being here today. I would have said that earlier, but I was in a rush to get my 1 minute in about a couple of things I am concerned about.

Something you mentioned earlier about the donut hole in Medicare part D, you said too many seniors have to pay because they get into this donut hole. Do all seniors pay that get into this donut hole or are poorer seniors at some level exempted from the donut hole?

Secretary SEBELIUS. Well, you don't actually hit the donut hole unless you extend beyond the limits that the initial provision of part D pays for.

Mr. BLUNT. I know that. So the seniors that get above that limit, do poorer seniors have to pay if they get into the donut hole, the poorest seniors?

Secretary SEBELIUS. I want to make sure I am giving you accurate information. They do not, sir.

Mr. BLUNT. They do not. And I think that number is, what is it, 135 percent of poverty; or is it a different number than that?

Secretary SEBELIUS. 150 percent of poverty.

Mr. BLUNT. So poor seniors don't pay. Under your proposal, would all seniors be exempted in this donut hole from having any expense?

Secretary SEBELIUS. Sir, we did not have in the budget closing of the donut hole. What I was referring to with the chairman is the provisions that are in both, and they are different in both versions of the Senate and House health reform legislation. Both majorities sought to close the donut hole, but our budget—

Mr. BLUNT. Well, since you talked about, can we talk about it for a minute? Closing the gap, among other things, suddenly there is no disincentive, it would seem to me, for all seniors, including the richest seniors, not to use generic drugs, not to look for an alternative product if there is no reason not to get into this high level of spending. What I have wondered about is if 150 percent of poverty isn't a good enough number to help seniors who can't afford it, what is the best number? This idea that all seniors, no matter how wealthy, deserve for the Federal Government, through part D, to help them pay for their drugs doesn't seem to really benefit the system or be the kind of reforms we need in Medicare generally. And I am just troubled by this idea that somehow all seniors are disadvantaged by this, and no matter how much money they have, they shouldn't have to worry about this donut hole.

Secretary SEBELIUS. Well, Senator—I mean Congressman, running for Senator Congressman. We would be happy to work with you if you would like to talk about a cap or a limit for applicability to close the donut hole. At this point I think there is no differential if you are a wealthy senior or a poor senior.

Mr. BLUNT. Well, of course there is a differential. You just said there was, 150 percent of poverty.

Secretary SEBELIUS. No, I am saying at the original benefits of the program there isn't a differential. I think if you are ill, if you are wealthy or poor you are likely, much more likely to hit the cap than if you are in great shape. It has I think more to do with someone's health and well-being than economic status.

Mr. BLUNT. I actually thought it had to do with the capacity to pay. The chairman said seniors should not have to go without their medicine due to lack of money. Now I don't disagree with that at all. I do disagree with the idea that somehow a problem that can't be solved any way other than eliminating this one area where you have to think about whether you get above a spending cap or not.

Mr. WAXMAN. Would the gentleman yield?

Mr. BLUNT. I don't have much time, Mr. Chairman. I don't think I probably can.

On the question of high risk pools, I don't know, Governor, if Kansas had one or not, Missouri says—and we have both used them and are both familiar with them. Do you have any idea why there is no money in this budget for high risk pools?

Secretary SEBELIUS. Well, Congressman, at least in Kansas, and I think it is true across the country, the Federal Government really provides very little in the way of support for—

Mr. BLUNT. On this budget they provide nothing.

Secretary SEBELIUS. I understand. It is about 2 percent. And what was anticipated with the passage of health reform that we would actually have a whole different situation with high risk pools. Many of the people in Kansas in high risk pools are those who are blocked out of the insurance market, because insurance companies refused to take them with preexisting conditions. Health reform solves that piece of the puzzle, they would have affordable coverage. So there was money in health reform for a new basis of high risk pools that could create some stop loss policies for those and a stop gap method between now and the time the exchanges are set up, but we anticipated that actually the high risk pool as they are seen right now, which is a very modest safety net, often way to expensive for most people to afford, would cease to exist. That is why the budget—

Mr. BLUNT. I think the percentage of the premium in Missouri is about 135 percent of what the normal premium would be. I would certainly be glad to work with you on, assuming where we are today on this issue, that we can figure out ways to expand access to the high risk pools.

Mr. Chairman, I am over my time.

Mr. WAXMAN. The gentleman's time has expired. Mr. Dingell.

Mr. DINGELL. Chairman, thank you. Again Madam Secretary, welcome. Madam Secretary, there have been a lot of scandals and unfortunate news about food safety and foods. You will recall last year this committee reported unanimously with the support of both sides. My Republican colleague Mr. Barton was one of the cosponsors as was our chairman and Mr. Pallone and other members of this committee. That was a bill which passed the House with an overwhelming vote and it is now sitting in—I hope in a position where maybe we could get it up to the floor so it could get to conference and we can pass it to law.

Do you have the authority you need now to protect the American people, yes or no, from unsafe food products both in this country and coming in from abroad?

Secretary SEBELIUS. No, sir.

Mr. DINGELL. Madam Secretary, I am very pleased at the commitment to medical product safety in the bill and also to food. Do you believe that Food and Drug authorities have the authorities they need to carry their regulation in the 21st century?

Secretary SEBELIUS. Not at this time.

Mr. DINGELL. Now in the bill that was introduced by my colleagues, I, Mr. Stupak and the others, it had a number of things, annual registration fees, increased inspections, strong new enforcement tools, greater responsibility for manufacturers to identify the control risks, tougher scrutiny of ingredient and raw materials supplies, documentation of safety for imported food products, and of course the ability to see to it that good manufacturing practices are followed around the world. Do you need that authority?

Secretary SEBELIUS. Yes, sir.

Mr. DINGELL. Madam Secretary, I note that that has some \$220 million in food registration and inspection user fees, that those are in the President's budget. Are they necessary for the Food and Drug Administration to carry out its proper responsibilities?

Secretary SEBELIUS. Yes, sir, I think they are.

Mr. DINGELL. Madam Secretary, we now confront a serious problem about health care data improvement. The President has included 110 million for comprehensive health care data improvement initiative at CMS. The initiative appears to be a key part of the Medicare and Medicaid delivery system reform puzzle. It appears that the administration is on to something here.

I have wrestled with a number of department agencies over the past of their adequacy and of their systems to upgrade these matters. They have had good motivation and noble intentions, but the implementation was also lacking, causing substantial waste and confusion.

Madam Secretary, regarding the 110 million, is this to be a one-time investment?

Secretary SEBELIUS. No, sir, this is I think a multiyear strategy to actually build a 21st century—

Mr. DINGELL. Should we anticipate, Madam Secretary, that you will be coming back up here to continue to move toward adequate resources to sustain this project over the years?

Secretary SEBELIUS. Yes, we will.

Mr. DINGELL. Madam Secretary, one matter of concern, will you provide the necessary and proper oversight of contractors and HHS employees responsible for seeing this project through?

Secretary SEBELIUS. Yes. And we finally have an information officer who also is helping us oversee this project who is not directly connected with CMS.

Mr. DINGELL. Madam Secretary, is your plan to consult appropriate stakeholders to ensure that all potential issues are properly identified and addressed?

Secretary SEBELIUS. Yes, sir.

Mr. DINGELL. And I am sure, Madam Secretary, that you will do the things that are necessary to ensure a smooth and effective transition.

Secretary SEBELIUS. It is my plan to do just that.

Mr. DINGELL. Madam Secretary, last year the President signed a monumental tobacco bill into law. I am pleased to see the administration's commitment to the FDA tobacco program in this year's budget. However, I have been concerned about the recent court activity surrounding FDA's actions related to tobacco products.

Can you give us a very brief update here and then further information and a submission for the record on the progress of the tobacco program and comment on the administration's thoughts on some recent unfortunate court decisions?

Secretary SEBELIUS. Well, Congressman Dingell, we are taking the responsibility to regulate tobacco products very seriously and I would say approaching them—

Mr. DINGELL. I am satisfied you are, but I note that the courts have just recently said you couldn't regulate electronic cigarettes.

Secretary SEBELIUS. Right.

Mr. DINGELL. I note that electronic cigarettes were set forth as a device, which is a device which would inject narcotics or drugs into the human system. I note that the court has held that they are not. I find this most curious. I note you have appealed this matter, and I ask do you need additional authorities to address that problem?

Secretary SEBELIUS. Well, once we hear back from the court we may well be back in Congress with some request for additional authorities, but we have a new center, we have a new director, we are publishing regulations. We have taken on the flavored cigarettes, we are looking at the avenues that were outlined by Congress. And when we hit a logjam we may well return to you for legislative clarification.

Mr. PALLONE [presiding]. Mr. Chairman, Chairman Dingell, I know your time is over and it is also that we have a vote.

Mr. DINGELL. My time is up. I am going to yield. Go ahead.

Mr. PALLONE. Thank you. We have two votes coming up and those are the last votes of the day. But I am going to try to get in two more people. So I just want everyone to know we are going to go to Mr. Deal if he is ready.

Mr. DEAL. Yes.

Mr. PALLONE. And then we will go to Mr. Engel and then we will break for the votes and come back.

Mr. DEAL. Thank you, Mr. Chairman. Mr. Chairman, I would ask unanimous consent to include in the record the letter of September 14th, 2009, which was the letter that Mr. Barton referred to that was addressed to the Secretary.

Mr. WAXMAN [presiding]. Without objection, that will be the order.

[The information appears at the conclusion of the hearing.]

Mr. DEAL. Madam Secretary, welcome.

Secretary SEBELIUS. Thank you.

Mr. DEAL. I am going to refer to a letter also. This is one that was sent to the Acting Administrator at CMS by Mr. Barton, myself, and Mr. Walden on June the 17th. It is a letter that asked for information as to the potential impact on State Medicaid programs with the proposed expansion of Medicaid under the House version of health care reform. And I would ask if you would—we have not received a response to this June letter and I would ask if you would please try to get us an answer to that.

Secretary SEBELIUS. I will do that, sir. We are collecting that data. It is not data that we hold and the States hold, and we are working on collecting that right now.

Mr. DEAL. Thank you.

In that regard the best I can determine and the best information that we can get from CBO is that the House version would add about 15 million Americans to the Medicaid rolls and would produce about \$34 billion in unfunded mandates on the States between the years 2015 and 2019.

Now you mentioned earlier you had been talking to Governors about other issues. I wondered if you have talked to any Governors who support this mandatory expansion of their State Medicaid programs and, if so, would you be courageous enough to tell us who they might be?

Secretary SEBELIUS. Sir, I have had lots of conversations with Governors. Clearly they would like as much help as possible on critical health needs, not only expended FMAP but if the Federal Government were to pay for 100 percent of Medicaid coverage on into the future they would be very grateful. They are appreciative of the notion that there are changes in the drug reimbursement

rules also anticipated. There are changes in the way that States would be treated in terms of qualifying for various services.

So we have tried on a case-by-case basis to give States regular kind of updates on what impact the various versions of various measures were and we will continue to do that.

Certainly the President's inclusion of the FMAP extension in his budget is an indication, I think, that he takes very seriously the States' situation with regard to FMAP. We are also working with a lot of Governors on the dual eligible situation, which is currently one of the more expensive populations that any Governor deals with and looking at ways through our current CMS authority that we can give more flexibility to States, more innovative abilities to coordinate and manage care and hopefully return some of those savings to States.

Mr. DEAL. As you may know, one of the provisions of the House bill, which is section 1703, with regard to expanded Medicaid and the enhanced FMAP, is the requirement that States enter into a maintenance of effort requirement. And our understanding is that that would prevent States from implementing any new procedures to reduce the prevalence of fraud in their Medicaid program, for example, because the language is that if it is more restrictive than the procedures in effect on June the 16th, 2009, and it may very well be that States would want to enhance their antifraud provisions and make it more restrictive than what was in effect last summer.

I wonder if as Governor of Kansas you would have taken very kindly to us telling the States that they would be prohibited from incorporating any new antifraud provisions into their State Medicaid program. And is that your interpretation of that section?

Secretary SEBELIUS. It certainly is not. I think that there is no question this administration and I think the Congress takes fraud and abuse very seriously. We have actually enhanced and have in not only the budget but in health reform a number of enhancements for fraud and abuse efforts. I think that the maintenance of effort language that you refer to has been in place since the Recovery Act was passed. It was defined to legislators—I mean to Governors. I was certainly as I say a Governor at the time. No one ever suggested that maintenance of effort meant that you could not enhance antifraud efforts in the State. And in fact we had very aggressive antifraud efforts in Kansas and have for years.

Mr. DEAL. Does the maintenance of effort requirement that was part of the stimulus money, does that requirement expire upon the expiration of the stimulus funds received by the States?

Secretary SEBELIUS. Yes, it does.

Mr. DEAL. Thank you, Mr. Chairman.

Mr. WAXMAN. The gentleman's time has expired. Mr. Engel.

Mr. ENGEL. Thank you, Mr. Chairman. Madam Secretary, welcome. I have three issues which I am going to raise quickly and I would like your comments on them. I chair the Western Hemisphere Subcommittee in the Foreign Affairs Committee, and I have been really grateful for all the wonderful support the Obama administration has given in the immediate and ongoing aftermath of the earthquake in Haiti, but as you know the hard work continues. We expect a great number of Haitians to join their relatives in New



York and in other areas of the country. We welcome these children and families, but we need to ensure the States and localities have enough resources to give them and our existing students the support and education they require. And as you know, our States and localities are already cash strapped during this difficult economic time.

Within the HHS Office of Refugee Resettlement, the Refugee School Impact Grant Program has stayed flat funded at \$15 million for the past 5 years, even in this year's budget which came out after the earthquake.

In a letter that Senator Gillibrand and I sent you yesterday, we asked if the administration would support either a one-time emergency grant program for school districts that receive a high influx of Haitians or alternatively if you would increase the funding for the Refugee School Impact Program. While the broader social services and refugee program which funds the school impact program was granted an extra 25 million in the fiscal year 2011 budget, your staff said the school impact program would be unlikely to see a bump in funding. I find that troubling. So I would like to ask you, would you commit to working with me on this important issue to give our schools and communities the support they need if there is an influx, and we know there will be, of Haitian children putting strains on school districts.

Secretary SEBELIUS. Congressman, we would be glad to work with you on all the ramifications of the Haitian situation, which as you know we are just beginning to try and sort out. But yes, I would be very happy to continue that dialogue.

Mr. ENGEL. Thank you very much.

Madam Secretary, the New York delegation last week or the week before met with you, and I thank you for meeting with us, and we had a very good discussion about 9/11 health issues. As you know when we had discussed it, all Americans 9 years after September 11th, first responders who came and were selflessly trying to save and help others now find themselves because of the toxicity of the air sick. We estimate there are about 20,000 people who are sick, coming from 431 of the 435 districts across the country. And some have died unfortunately, others are disabled.

We were hit, New York was hit, not because we were New York, but because we were a symbol of this country, and it is an ongoing fight in the war against terror. We had had a discussion about whether the administration would commit to funding in the bill the health that we need—the health care that we need for this bill. I know we are talking about it.

So I am going to ask you if you would commit to working with us to pass comprehensive 9/11 health care that is paid for.

Secretary SEBELIUS. I would very much like to work with you on that issue. As you know, the President's budget doubles the amount of funding in the project for 2011 and we look forward to working with you and others in the delegation on a long-term permanent solution.

Mr. ENGEL. Thank you. My final question, in last Congress the ALS Registry Act, Lou Gehrig's disease, a bill that I authored with my friend Lee Terry on the other side of the aisle was signed into

law. It came through this committee, it had great bipartisan support and over in the Senate as well.

I was disappointed though to see that the administration cut the ALS registry's funding by over \$200,000 in fiscal year 2011 from what Congress appropriated last year. And Congress did not appropriate the full money. The act was authorized for over \$10 million per year and it is funded at just under 5.8 million. So to take 200,000 away from the underfunding of 5.8 million is something that is very disappointing.

So I will ask you again, will you continue to work me and with Congress to ensure that the CDC has the resources it needs to fully implement the ALS registry?

Secretary SEBELIUS. We are aggressively, Congressman, moving toward the implementation of the full registry which we anticipate having online at 2011. The full funding that you refer to, the \$10 million, is not essential during the planning phases, and the cut that you are referring to is really out of travel and some contracting cuts that the leadership of the CDC felt could be made without at all jeopardizing the implementation timetable or the full implementation of the registry. So we would look forward to working with you on that.

Mr. ENGEL. Thank you. And Mr. Chairman, may I just ask unanimous consent that my letter to Secretary Sebelius on the funding for the HHS Refugee Resettlement Office be included in the record.

Mr. WAXMAN. Without objection, that will be the order.

[The information appears at the conclusion of the hearing.]

Mr. WAXMAN. Madam Secretary, we are going to take a recess. We have two votes, and as soon as we have completed the two votes we will come back and reconvene.

Thank you.

[Recess.]

Mr. WAXMAN. The committee will come back to order. Who seeks recognition? The gentleman is recognized.

Mr. WHITFIELD. Mr. Chairman, thank you. And Madam Secretary, we appreciate you taking time to be with us this afternoon. Last weekend President Obama came over to Baltimore to meet with our caucus and I am sure you read some about that. One of his comments that he made, we were talking about the right to keep your current insurance policy if this health care reform bill passes. And he said, I think some of the provisions that were put into this bill have violated my pledge to allow people to keep their insurance if they want to keep it. And when I look at section 202 of the House bill, which is about 3 or 4 pages in that section relating to protecting the choice to keep current coverage, there are all sorts of exceptions in here. And one of the frustrating things that I personally have is we keep hearing this you can keep your coverage, you can keep your coverage, you can keep your coverage. And even the President said there were provisions put in at the last bit that cannot guarantee that.

Now is that your understanding, that there is no guarantee that a person can keep their current insurance coverage if this bill passes?

Secretary SEBELIUS. Well, Congressman, I can't speak for exactly what the President was talking about. I do know that in today's

market nothing ensures an employee that his or her employer is going to continue employer based coverage. Nothing ensures that if you have employer based coverage that that employer will use the same network or the same doctors. That changes every day with contracts. So I don't know if that is what he is—I really don't know. But clearly there is not a way to guarantee. I think that the attempt has been to say we are not mandating anybody have to move——

Mr. WHITFIELD. I really appreciate your saying that because, to use his exact words, he said some of the provisions that were snuck in have violated that pledge. And when we hear people emphatically saying you have the right to keep your existing insurance policy, that is really not true. And so I am delighted that you clarified that——

Secretary SEBELIUS. In the current market, I am saying absent any health reform legislation, no one is sort of guaranteed that.

Mr. WHITFIELD. Right. One more comment I would make, if this bill passes we know that the coverage for Medicaid is going to be expanded, so the States normally pick up that cost and we are trying to provide additional funds from the Federal Government because the States need it. The fact that bothers me about that is that the Federal Government needs money, too. So basically we have a program here that is expanding, that is going to cost the States more money. And because they need more money from us, it is going to cost the Federal Government more money.

But the part of this process that has bothered me the most, and I think because I have heard so many comments from people not only in my district but really from all over the place, and that is the whole process when you are endeavoring to comprehensively change the health care system in America and you see side deals being cut, when all of us represent the same taxpayer and you see Nebraska getting a special deal, you see Vermont getting a special deal, you see Massachusetts getting a special deal, you see three counties in Florida where they are able to keep their Medicare Advantage program and yet in my district we have 15,000 people on Medicare Advantage that may not be able to keep theirs because of the reduction in money available for Medicare Advantage. It is just patently unfair.

And I am assuming that HHS worked with some of the staff on cutting some of these deals, which we understand is done to obtain votes, but as a citizen does it bother you that if you are in a certain State or you are in a certain county that you get benefits that other taxpayers simply are not going to be able to have?

Secretary SEBELIUS. Congressman, I think that unfortunately it seems to be endemic of any legislative process that money is never distributed exactly equally and it always is a problem for those who don't get the resources, and I think this is no different. But it has been my experience that that is unfortunately a pattern, whether it is appropriations or where projects are sited, or who is on the committee, there often is not an actually equal distribution of any course of resources, and I think it does make people unhappy.

Mr. WHITFIELD. I think so, too, and I think that the one area where we should get away from that is in the health care area.

Thank you very much, Mr. Chairman.

Mr. PALLONE [presiding]. The gentlewoman from California, Ms. Eshoo.

Ms. ESHOO. Thank you, Mr. Chairman. And welcome, Madam Secretary. It is wonderful to see you. A warm welcome to our great friend who was with the committee for years and I think will always be part of this family, and that is Bridgett Taylor. It is really great to see you.

Madam Secretary, thank you first for—

Secretary SEBELIUS. She is now part of our family.

Ms. ESHOO. That is right, that is right, but she was a long-time member of ours. You are lucky to have her.

Thank you for your very, very thorough responses to letters that I wrote to you. I appreciate that. It took some time to get the responses, but they were worth waiting for because there were direct answers about exploring the use of adjuvants and vaccines and thimerosal as well as promoting the new generation of subculture-based vaccines and on the issue of BioShield and BARDA.

It is more than refreshing to see an HHS budget that emphasizes science. We have gotten away from it in our country for too long. I think we paid a price for that because time is really the most precious thing that we are given. And for almost a decade we lost that time relative to science. So rather than applying political science we now are honoring science, and I think that that really honors the American people.

I also would like to applaud many different parts of the budget because they are, I believe—and this budget is most frankly what I hear from my constituents, from my constituents mostly about. Most of the e-mails, questions, factions, meetings have something to do with your budget, with HHS. So I think it is a good one.

Now, on the issue—I know there is an emphasis on fraud and an effort to root it out, which I think is really very important. The last time we visited that is in the Clinton administration. That is a long time ago. I remember Secretary Shalala sitting there and describing for us what they were undertaking.

How much of a return do you expect from the HEAT effort and I know that there is \$1.7 billion invested in that. What do you think the return is going to be?

Secretary SEBELIUS. The most conservative estimate I would say is that we get somewhere from \$1.10 to \$1.50 on every dollar invested. The Attorney General's numbers look more than 4 to 1. Our actual experience with the current fraud efforts are that we get somewhere between \$14 and \$17 for every dollar invested. So we have a wide range. What we know is we get back more than we spend.

Ms. ESHOO. Well, it is an area that is galling to the American people. There have been things on 60 Minutes, you know, these store front ripoffs. It really is the private sector ripping off the public sector. But I think that this HEAT effort better be white hot because there is a lot of money to be found in this, and I wish you well on that.

The other area that I want to ask you about is the area of, as I mentioned earlier, on BioShield and BARDA. There have been dollars that have been moved around, not a lot but you have

moved, I think, 36 million or 136 million out of one area to another, and that is the—what I am concerned about is the SRF and you have moved some funding out of that. Admittedly it is not a ton, but I worry about what remains because the whole area of developing and acquiring chemical, biological, radiological, and nuclear medical countermeasures is very important for our country. I mean we have just gone through H1N1. I think that is something that will look like something out of a seed catalogue, God forbid, if our country, God forbid, had to endure a bio attack.

So are you comfortable with that? I mean why the movement of the funds, how much is left?

I know that you said in your prepared remarks that there is going to be a report due on March 31st of this year. Maybe we can revisit this when the report comes to us. If you could see that the committee gets that ASAP when you put it out. But it is an area that Mr. Rogers and I both worked on, and I have a continuing interest in it both from this committee's standpoint and also from the other hat that I wear from the Intelligence Committee.

And lastly, I want to say something, I know that—let me just say this.

Mr. PALLONE. The gentlewoman's time is over, but go ahead, finish.

Ms. ESHOO. I am going to take about 30 seconds. And that our colleagues on the other side of the aisle are continually banging on all kind of drums relative to health care, all kinds of ideas, offer everything to everyone, cure everyone, give everyone insurance, and it is not going to cost a cent. I don't know where your budget is on this, but I think you need to put it on the table.

Furthermore, most frankly, you were in control for a long time and you are on this committee that has—

Mr. PALLONE. The gentlewoman is a minute over.

Mr. GINGREY. Regular order, Mr. Chairman.

Ms. ESHOO. Why didn't you pass all these things when you were in control?

Mr. GINGREY. Regular order.

Mr. PALLONE. Move on.

Ms. ESHOO. Answer the question. You don't like it when someone raises it.

Thank you, Mr. Chairman.

Mr. PALLONE. Gentleman from Illinois, Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman. I think that the benefit of having the President in Baltimore is that we did give him the package of gop.gov and I want to encourage my colleagues on the other side to take a look at those, because I do think, Madam Secretary, when we met with the RFC before the bill moved to the floor, I did talk about private insurance, a national health exchange, and a way to do it on a market based solution. The Democrat leadership did not decide to go in that manner. I hope we relook at that. If we really want to move legislation and provide health care to all Americans, there is a compromise out there and you can model it out a Medicare D. That is what I proposed, I don't know, a year ago, or 8 months ago, but we could really get there if we shelve the centralized control, one big government solution and go back to the market.

But for my questions, according to the Congressional Budget Office, the House-passed health reform bill would add 15 million Americans to the Medicaid rolls, producing 34 billion in unfunded mandates on States during the 2015–2019 period. Now this is following up from Mr. Deal's question, which he asked has any Governor said, no, this is a bad idea. You failed to answer that question, and I am wondering if based upon—did you have any Governor say I don't want these additional unfunded mandates because we know Medicaid requires the State, some States a 50/50 share, some States 70/30 share, depends on the State. Do you have any Governors that said no, don't do this, the Medicaid expansion is bad, we can't afford it?

Secretary SEBELIUS. We have had Governors who have expressed that they want more adequate Federal funding if there is expansion and other Governors who are very enthusiastic about the plan. So we have had both.

Mr. SHIMKUS. So there are 35 States right now moving referendums against this, and I think the Virginia Senate just passed legislation through the Virginia Senate against the expansion of Medicaid.

Secretary SEBELIUS. My understanding is the Virginia issue deals with a mandate to purchase insurance coverage.

Mr. SHIMKUS. Well, I think that 35 States—yes, we can address that, but the issue is States are saying no, they can't afford it. Illinois is broke, California is broke.

Secretary SEBELIUS. And many States, as you know, Representative already exceeding the 133 percent. So we have States that are kind of all over the place.

Mr. SHIMKUS. I would just say expanding Medicaid to States who can't afford to expand it by mandate, and that is where the debate comes, so then the Federal Government, which doesn't have a balanced budget requirement that many States do, that is where then we pick up the tab and we go into historic national debt as we find ourselves today just passing an increased—it is not mine—an increase in the debt limit.

Let me go to—would the President sign the Senate health care reform bill into law as it is alone?

Secretary SEBELIUS. Sir, you would have to ask the President. Maybe you did in Baltimore.

Mr. SHIMKUS. Let me set the groundwork. When you came here the first time the health bill was just in draft form, so you refused to take any questions on the health reform bill. You promised to return, which that never happened. So a lot of the frustration today is not having a chance to talk to you in the committee process to debate health care reform that was going to go through this committee. So that is where a lot of this angst and now we are only given 2½ hours to—no one is allowed to give opening statements as a whole and then we are—yes, they did extend it for an hour, but we had votes, two votes in between. And that is part of the incredible frustration here.

So does the President support cutting half a trillion dollars from Medicare as do the Senate and House reform bills?

Secretary SEBELIUS. Does—

Mr. SHIMKUS. Yes or no? I will use the John Dingell approach, yes or no.

Secretary SEBELIUS. The President supports the health reform bill.

Mr. SHIMKUS. So he supports cutting \$500 billion from Medicare?

Secretary SEBELIUS. He supports making sure that Medicare is solvent into the future.

Mr. SHIMKUS. So that is a yes. The President supports cutting 500 billion? The Senate bill says 500 billion, the House bill says—

Secretary SEBELIUS. Well, they had different numbers in them, but the President—

Mr. SHIMKUS. So the President supports cutting \$500 billion in Medicare, yes or no?

Secretary SEBELIUS. The President is supportive of the health reform legislation.

Mr. SHIMKUS. Is that a yes?

Secretary SEBELIUS. I said yes, sir.

Mr. SHIMKUS. OK, thank you.

Let me just talk about one issue that was hit on with Mr. Whitfield. These three counties are what we talk about as Gatorade, the negotiated deal that Florida cut for their Medicare Advantage folks. These three counties, Palm Beach, Broward and Miami Dade, will not feel the effect of the Medicare cuts for Medicare Advantage. Was HHS involved in negotiating this deal with the Senate?

Secretary SEBELIUS. Sir, I was not—

Mr. SHIMKUS. No HHS staffer was involved?

Mr. PALLONE. The gentleman's time is over.

Mr. SHIMKUS. Thank you.

Mr. PALLONE. Sure.

The gentleman from Texas, Mr. Green.

Mr. GREEN. Thank you, Mr. Chairman. And welcome, Madam Secretary. And obviously our country has had a problem with excessive spending for decades. And I hate to keep reminding our colleagues on the Republican side, we had a balanced budget in 1999 and 2000 and we ended PAYGO the next year or two, and literally for the first part of this decade, for the first 7 years, we spent without worrying about it, everything went to the national debt. And now we are trying to do so many things with 10 percent unemployment.

Let me get back to health care and the President's budget. First of all, I appreciate you being a longtime champion to community health centers and the sponsor of the most recent health care center authorization. And as the sponsor of the most recent health care reauthorization that passed our committee in 2008, I want to commend the President's budget for the proposed increase in health center funding. Although it is below the amount we have authorized given the physical constraints you are working with, I am very much appreciate this increase. I am especially grateful the administration appears to propose that a portion of this increase goes toward ensuring that operating funds that health centers receive through the Recovery Act will continue. I know in my own district a number of our community-based health centers expanded, see more patients and are actually hiring personnel. It was part of

the stimulus bill. Health centers to date extended care to 1 million Americans using this funding and expect to surpass their goal of two million new patients by the end of the stimulus period.

Can you confirm for us that you intend for existing health centers to continue to receive the funding in order to maintain the capacity to care for the new patients they have added over the past year?

Secretary SEBELIUS. Certainly, Congressman, it is our intent to provide resources so that the health centers can deliver care to the 20 million people.

Mr. GREEN. Of course community-based health centers really is a bipartisan issue. President Bush suggested increases that we tried to match. Because the district I represent has the highest uninsured rates in the country, I want to significantly expand the health centers program because of their 40-year track record for providing high quality and cost effective care. I support the efforts of the President to continue access to care for those two million served by the health centers through the stimulus bill and to continue to grow the health centers program by providing the \$290 million increase that is in the budget.

Would you agree that this funding request is based on what you see is possible through the limitations and the discretionary appropriations process that is even more significant growth through dedicated funding or has been proposed in both the House and Senate reform bills is still necessary, that growth is still necessary even though we have seen both the House and Senate health care bills?

Secretary SEBELIUS. Well, I absolutely think that delivery of primary care services through community health centers is one of the great success stories. Low cost, high quality care, and really dealing with the whole family. So I am very supportive, I try to visit those centers wherever I go in the country, and they are remarkable, community based centers that deliver high quality, lower cost primary care.

Mr. GREEN. If we get to pass the health care bill, I consider that the boots on the ground is our community-based health centers throughout the country.

I also appreciate you being an outspoken proponent that schools can play in vaccination, both with seasonal and pandemic influenza and appreciate your leadership on that. I do have some concern, in 2008 I was the sponsor and we passed the Tuberculosis Elimination Act. I strongly support increased funding for TB. TB is the second leading global infectious disease killer and because it is an airborne infectious disease it has always been a present danger in the U.S.

Many States, such as California and Texas, where I represent, are struggling with steady increasing rates of drug resistant TB, which is extremely costly and complicated to treat. Yet the TB will receive a funding cut under the President's proposed 2011 budget. Public health history in the U.S. has shown that cutting back on TB control programs can cause costly resurgence of the disease such as happened in the U.S. in 1988 to 1992, when New York City had to spend over a billion dollars to regain control over TB.



Can you assure us that the States will adequately be equipped to protect our communities if we have outbreaks, additional outbreaks of the drug resistant tuberculosis.

Secretary SEBELIUS. Congressman, I look forward to having a chance to visit with you more about this issue where you clearly have some considerable expertise. Our new Director of the Centers for Disease Control and Prevention, Dr. Tom Frieden, did a large portion of his work on TB. He takes it very, very seriously. So I think working with him and you to make sure we have the resources available is something that I am committed to doing.

Mr. GREEN. Again, thank you for being here.

Mr. Chairman, I actually didn't ask for any extra time.

Mr. PALLONE. I appreciate it. Thank you.

The gentlewoman from California.

Mrs. BONO MACK. Thank you, Mr. Chairman. And Madam Secretary, welcome. I have two brief questions that I would appreciate your insight regarding two requests I have pending before your Department.

Right now at least two and a half million adolescents suffer from substance abuse disorders and surveys sponsored by your Department showed continued and increasing trends of the abuse of prescription drugs like Vicodin, Xanax and in my opinion the very powerful and deadly OxyContin. This problem has been largely ignored in the health care reform debate. I have concerns that proposed generalized programs like the Prepared Communities Program and counterparts at the DOE will dilute the important focus on drug addiction and prevention.

So my first question for you is will you ensure that a clear focus remains on strategies aimed directly at preventing drug use and underaged drinking?

Secretary SEBELIUS. I look forward to working with you on that, absolutely.

Mrs. BONO MACK. Thank you.

Last year, I asked the FDA—late last year—some specific questions regarding a new formulation which, from what I am hearing, it is not tamper-proof, actually it might allow the drug OxyContin to be more abused. So I wrote a letter to the FDA with these specific questions, given the tragic abuse of prescription drugs among our Nation's youth. I am hopeful you can encourage your staff to respond to this inquiry.

Secretary SEBELIUS. I would be very happy to do that. And Congresswoman, I would like to also have our new Director of the Substance Abuse and Mental Health Administration get in touch with you. As you probably know, substance abuse with prescription drugs is only slightly behind alcohol abuse right now and rising dramatically among children. It is an issue that she takes very seriously, has done a lot of work on. We are using her to help inform a number of our outreach and strategy efforts. So again, I think it is going to be a renewed and specific emphasis throughout our Department.

Mrs. BONO MACK. I am encouraged to hear that, and I thank you. I think it is very, very important for us to do that.

Finally, I request your assistance with an issue that is important to our shared goal of rooting out waste, fraud and abuse. In my dis-

tract, the 45th District of California, a tribal TANF program is operating, and the tribe has received over \$30 million a year, on average, to administer this program. It is troubling that government audits have shown a repeated misuse of Federal taxpayer dollars, including Federal allegations of misuse of \$6 million alone in 2002 and 2003. Years later, penalties assessed to the program have still not been resolved.

I recently requested that the IG at HHS and ACF investigate this matter further. The IG stated that the concerns would be best addressed by ACF. Knowing the charge of the IG's office, I hope that they and the ACF can aggressively seek answers and come to a resolution of what appears to be years of insufficient accounting and a wasteful use of taxpayer dollars. I fear that prolonging this problem only hurts the Native Americans for which this program was designed to serve in this difficult economy.

Are you willing to consider protecting taxpayer dollars by withholding new funds until the situation can be resolved?

Secretary SEBELIUS. Congresswoman, I must confess, I am not aware of this situation, but I will commit to going back and dealing with both the head of ACF and the IG's office and putting together the information. I can't commit to anything until I know what the situation is and what the history is, but I will definitely take that as a personal commitment.

Mrs. BONO MACK. Thank you very much. I think it is extremely important. It is a very blatant example of this waste, fraud, and abuse, and it is hurting the people that are designed to be helped by this kind of a program.

Lastly, I am sorry that my colleague from California left, Ms. Eshoo. I just would like to say that her questions about what has happened in the past on health care really ring hollow to my constituents; they care about what is happening today. And I can tell you that they do not like government takeover of health care in any way, shape or form. But I am sorry that she has left, but I did need to say my frustration as well that pointing the finger, my constituents are tired of that argument. They want to have answers, and government takeover of health care is not what they want to hear.

So I appreciate your being here today, and I look forward to working with you in the future.

I yield back the balance of my time.

Mr. PALLONE. Thank you.

Next is the gentlewoman from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. And thank you, Madam Secretary, for being here and sticking with us this afternoon.

I wanted to just make a comment about the exchange that you had earlier on the issue of the donut hole. I wanted to make it very clear that as important as the low-income assistance is for people up to 150 percent of poverty, we have to understand how low an income that is and what difficulty people over that—150 percent of poverty is \$16,250, and to suggest that seniors that make that much money can even think about getting out of a donut hole that is \$3,500, it doesn't really compute for me if you think about the other expenses.

So based on your experience, is a \$3,500 coverage gap just for prescription drugs—that doesn't count premiums and copays—just for prescription drugs affordable for someone whose income is \$16,500?

Secretary SEBELIUS. Well, certainly not at that income level. And while there may be, as I told the Congressman in his follow-up discussion, some individuals at a very high income level, I think typically we are talking about people using prescriptions who tend to be sicker needing more medicine, which also is often a problem because they are spending more expenses on all kinds of other areas. So 150 percent of poverty is not a wealthy senior.

Ms. SCHAKOWSKY. Is \$20,000 a year—I would even ask if \$35,000 a year, if that is what you make, to get out of the donut hole at about \$3,500. These prices are exorbitant, and as you say, these are the sicker people.

Secretary SEBELIUS. Well, unfortunately, what at least my experience is working with seniors, is that too often there really is not a great deal of understanding of what is going to happen. So filling that next prescription, you are suddenly out of any kind of assistance, and you go from paying—and you continue to pay your premium for part D.

Ms. SCHAKOWSKY. Absolutely.

Secretary SEBELIUS. So you pay a premium, and you are paying out of pocket 100 percent of the cost. And I know what happens all too often is people just don't fill the prescriptions, do not take the medicine, and can't keep themselves out of the hospital.

Ms. SCHAKOWSKY. That is why I prefer the House bill, of course, that actually does eliminate the donut hole altogether.

You may not have the answer because it is kind of an esoteric question, but I want to pose this to you and maybe you can get back to me. We have some nursing home reform advocacy groups in Illinois, Illinois Citizens for Better Care for one, and this is a problem that was brought to my attention. Recently there was a change that means they can no longer obtain Aspen survey data on disk, but have to get case-by-case reports on paper, which is a big cost burden and time burden to them. So I hope that you will review that decision in order to reduce the burdens on small not-for-profit groups that do inspections, they monitor how nursing homes are doing—and of course it is a huge problem—quality care in nursing homes, and to ensure transparency. So if you could just look into that.

Secretary SEBELIUS. We will be glad to and get back to you about that.

Ms. SCHAKOWSKY. Thank you. I yield back.

Mr. PALLONE. Thank you.

Mr. Terry is next.

Mr. TERRY. Governor, I appreciate you being here.

First of all, what is your understanding of where the health care legislation is today? Are there plans that you are discussing with the White House and congressional leadership to move the House bill or the Senate bill? Or is there a movement that you are aware of to throw those two away, start anew, where we could focus on consensus items?

Secretary SEBELIUS. Congressman, I think there are lots of discussions going on. As you know, the House passed a bill and the Senate passed a bill——

Mr. TERRY. I asked you what is your understanding, not what other people are doing.

Secretary SEBELIUS. I am telling you what my understanding is.

Mr. TERRY. I am sorry, you said that you didn't know what other people were doing, so——

Secretary SEBELIUS. No. There are lots of discussions going on.

Mr. TERRY. So you are not going to answer the question?

Secretary SEBELIUS. There are lots of discussions going on. That is the answer to the question. There is no one single discussion——

Mr. TERRY. OK. Then would you be specific about the ones that you are involved with, what are the options? I am sorry, I wasn't more clear in my question evidently.

Secretary SEBELIUS. Congressman, I think no matter who you talk to, any number of options are on the table, start again——

Mr. TERRY. What are the options that you are advocating?

Secretary SEBELIUS. I don't have a single advocacy piece other than let's move the health reform forward. I favor, as the President does, a comprehensive plan. I favor looking at the similarities in the House and Senate version and hopefully finding a way to move comprehensive legislation forward as quickly as possible.

Mr. TERRY. OK. During the exchange with the gentlelady——this wasn't on my list to ask, but I have to now——

Secretary SEBELIUS. Which gentlelady?

Mr. TERRY. Ms. Eshoo. There was a comment that you agreed to that in regard to looking for fraud, nothing has been done since the Clinton——

Secretary SEBELIUS. Sir, that was her statement——

Mr. TERRY. Well, you agreed with it.

Secretary SEBELIUS. I sat here.

Mr. TERRY. Well, let me ask you; do you agree that the Bush administration has done nothing in 8 years to find fraud and waste? Because that was the statement, and you didn't counter that at all.

Secretary SEBELIUS. Sir, I don't have any expertise on what the Bush administration did or what the Clinton administration did. I assume that——

Mr. TERRY. Is it your opinion they have done nothing?

Secretary SEBELIUS. It is not my opinion one way or the other. I don't want to offer opinions.

Mr. TERRY. Well, you didn't correct the gentlelady, so I assume since you had the opportunity to say there has been efforts. Well, with the HEAT program in place, wouldn't it be beneficial that you looked at what past administrations have done?

Secretary SEBELIUS. We certainly have looked at what past administrations have done. I know——

Mr. TERRY. So what has the Bush administration done? You just said you didn't know.

Secretary SEBELIUS. I am very sorry. I am happy to go back and document. I don't want to give you incorrect information. I am not an expert on what the Bush administration did, or as Congresswoman Eshoo said, what the Clinton administration did, so I didn't

enter into that discussion. I would be happy to come back and report to you.

There clearly has been a fraud and abuse effort underway. There never has been the effort put forward by this President which asks the Justice Department and HHS to collaborate and cooperate at the Cabinet level to put strike forces on the ground to try to get out ahead. It has been a pay-and-chase operation, often auditing sometimes well after the fact has been in place for a long time.

Mr. TERRY. OK. Well, very good.

I have had some of my pharmacies back home tell me they have yet to get their inspections, even with the extension that Congress passed, to allow them to get their appropriate license to sell durable medical goods. Is there another effort by HHS to give them an opportunity to get licensed or whatever the appropriate language would be? It has already been extended once.

Secretary SEBELIUS. I can't answer that specifically, but I would be happy to get back to you. I don't know the reference, the time frame that you are referring to.

Mr. TERRY. Well, I only have 28 more seconds.

Lastly, in the environmental health section of the budget, it is reduced a little bit. There are two programs in here that I would appreciate you taking a look at, one is the Healthy Homes Child Lead Poisoning program. That is an extremely important program in Omaha. We are a Superfund site for lead, but if you ask our health folks, they will tell you that most of the lead poisoning that is occurring is from unhealthy homes that are significantly older than 1973. So for that to be one of the programs cut is a concern to me. The other is the ALS registration, which seems to be already below what the CDC has said they need to do the registration, and that is one that is cut.

One that is a new program put in—it seems to be sucking up a lot of the money from the programs that are cut—is the Built Environment and Health Initiative. Can you tell me what that is?

Secretary SEBELIUS. Congressman, I am sorry, I cannot, but I would be happy to get that answer back to you.

Mr. TERRY. I am just curious. Thank you.

Mr. PALLONE. I thank the gentleman.

Next is the gentlewoman from the Virgin Islands, Mrs. Christensen.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. And thank you, Madam Secretary, for being here.

We appreciate the increases that we are seeing in the 2011 budget, and hopefully we can do some more with health care reform as we move on from here.

You know of our commitment to stopping the preventable early excess deaths in African Americans and other people of color, and yet as I try to get a handle on what is happening in the Department, I seem to sense a moving away from focusing on racial and ethnic minority populations in the Department's efforts to eliminate these huge disparities that have existed far too long.

So one of my questions, which applies to the Office of Minority Health, the National Center for Minority and Health Disparity Research and the National Minority AIDS Education and Training Center, can you reassure me that the needed focus on the racial

and ethnic minority populations will continue—not because they are minority populations per se, but because they are so disproportionately burdened by disease, and would you support, as we are trying to do in health care reform and in other stand-alone bills as well, the strengthening and expanding of the Office of Minority Health to other agencies and the elevation of the national center at NIH to an institute?

Secretary SEBELIUS. Congresswoman, I would definitely commit to you that there has been no lack of focus or attention or interest in closing the gap in health disparities, which continue to be alarming and appalling. The new Assistant Secretary of Health, Dr. Howard Koh, also takes that very seriously. He is the umbrella agency supervising a number of the offices that you have just described.

Mrs. CHRISTENSEN. So the Office of Minority Health, for example, will stay Office of Minority Health; it is not going to not change the disparity and move away from minority that you know of. It is going to stay Office of Minority Health. The Office of Minority Health will continue to be the Office of Minority Health?

Secretary SEBELIUS. Yes.

Mrs. CHRISTENSEN. With all of the other AIDS Education and Training Centers open to everyone, and given the need for cultural competency and the fact that 70 percent or more of the patients with HIV and AIDS are people of color, we have this one National Minority AIDS Education and Training Center, it works with all of the minority-serving institutions, community-based organizations, race and ethnicity, but it seems as though HRSA is changing how they are dealing with this particular center, trying to fix something that is not broken, putting barriers in the way of minority-serving institutions, continuing to provide the service at a time when minorities are still disproportionately burdened by HIV and AIDS.

So do you know yourself what is happening within National Minority AIDS Education and Training Center; is there a move within your Department to open that up to every majority institution, better funded, better able to compete, or can we try to keep that within a minority-serving institution?

Secretary SEBELIUS. Well, again, Congresswoman, I think the very good news is that President Obama has taken very seriously the commitment to have a very aggressive domestic AIDS/HIV agenda, feeling that while the focus of PEPFAR has been a great success globally, we have really not paid as careful attention to what was happening in the United States. And as you just stated, the overwhelming number of new infections and new cases are focused directly in the minority community, in African Americans, in Latinos, and in American Indians.

First, I would tell you that I just participated in greeting and swearing in the new PACHA Council, a diverse and very committed group of individuals. We intend to have a very aggressive focus that is well funded, and our office is clearly a part of that. And I will have that conversation with Dr. Wakefield.

Mrs. CHRISTENSEN. Understanding the need to focus on racial and ethnic minorities, who are hardest hit.

I would just like to get in a word about ADAP, \$20 million this year, \$20 million next year. They need more than \$200 million to

end the waiting lists. We would like to see a stronger commitment to ensuring that everyone with HIV and AIDS has access to treatment and not lose sight of the fact that not only will people die as they wait on these waiting lists, but that treatment is a major form of prevention as well. So it is very important that we try to close that gap for ADAP.

Mr. WAXMAN. The gentlewoman's time has expired. Thank you. The gentleman from Texas, Mr. Burgess.

Dr. BURGESS. Thank you, Mr. Chairman.

Madam Secretary, last week—I hope you are aware that this committee took up the business of a resolution of inquiry to obtain documents from the White House and from your Department on deals that were made with six major stakeholders early in the health care reform debate. Thanks to Chairman Waxman, we had a unanimous vote in this committee in support of obtaining many of the documents that I think the committee really should have to see how the legislative process might have been circumvented. So Chairman Waxman and Ranking Member Barton will be delivering to you a letter detailing the six areas where we would like more information.

Do I have your commitment to work with Chairman Waxman and this committee to obtain those documents from your Department?

Secretary SEBELIUS. Yes, sir.

Dr. BURGESS. Thank you.

Now, yesterday you testified at Senate Finance that you and your staff were not enveloped in health care reform negotiations. Was that correct testimony to the Senate Finance Committee yesterday?

Secretary SEBELIUS. Congressman, what I testified to was that I don't have a vote in the committee. I have certainly been present at not only dozens of conversations with Members of Congress and the White House, I have traveled all over this country talking to stakeholders and seniors, doctors and nurses, teachers, union members. I have been involved literally in hundreds of meetings—

Dr. BURGESS. I am sorry. I am going to interrupt you because time is going to run out. It was reported in the New York Times yesterday quoting you, "I am not a principal in the negotiations." So you were present, but—

Secretary SEBELIUS. What I said is we play a role of providing technical advice and assistance. We certainly have encouraged people, but I don't have a principal's vote. I have been a member of the executive branch and the legislative branch, I am not a legislator at this point.

Dr. BURGESS. I am not meaning to interrupt, but in Politico on December 2, it was reported that there were strategy sessions that involved yourself, Interior Secretary Ken Salazar, White House health czar Nancy-Ann DeParle and White House Deputy Chief of Staff Jim Messina. Is that an accurate reportage, is that an accurate assessment?

Secretary SEBELIUS. I have no idea what they are referring to. I have certainly been in a room with those folks. And again, I will go through my calendar and give you information.

Dr. BURGESS. That gets then to my question, will you be willing to provide us any notes or e-mails that you had, for example, with the health care czar Nancy-Ann DeParle or the White House Deputy Chief of Staff, Jim Messina—

Secretary SEBELIUS. Sir, I will look at the request as it comes to me and assure you we will get back to you.

Dr. BURGESS. Well, here is the frustration, we are the committee that is charged with writing the legislation. And the President, to his credit, last March said that he was going to set boundaries and deadlines, but the committees were going to write the legislation. And then we find out that last May and June there were all kinds of deals cut with American Hospital Association, AHIP and PHARMA down at the White House, the AMA. We don't get to be privy to any of those deals. The AMA endorsed the bill before we even got it in committee. What did they give, what did they get? Why did that happen that way? Why was it in the Senate Finance Committee last fall that Senator Nelson, when he was trying to work some of the cost cutting that was going on, the whole bill had to go back to CBO to be scored because the hospital said we had a different deal?

You can understand the frustration at the legislative side with trying to deal with legislation that is this complex—and we all agree that it is complex—and yet we don't know on the legislative side what deals you have made on the administrative side. So that is very frustrating. In fact, I think it disrespects the role of this committee to not be privy to those discussions that were carried on behind closed doors, especially when the President promised over and over and over again that this would be a transparent process—you mentioned that in your opening statement, that transparency was going to be critical, and yet we have had nothing that resembles transparency, everything has been opaque from the administration in regards to how these health care deals were worked out.

Secretary SEBELIUS. Well, again, Congressman, I would suggest this conversation basically has gone on for a year. There have been hundreds of hearings, lots of C-SPAN coverage, lots of public forums and town hall meetings over and over and over again, three different committees have now tons of amendments—

Dr. BURGESS. I am well aware of that, I don't need to hear that recitation. But the Senate confirmed you as the President's principal health care advisor; is that correct? You went through the Senate confirmation process?

Secretary SEBELIUS. Confirmed me as the Secretary, yes.

Dr. BURGESS. Then it seems like—and what you tell this committee, what you told Mr. Terry is, well, you are really not a principal in these negotiations. Is that because the President doesn't trust you to carry on this type of negotiation?

Secretary SEBELIUS. Congressman, what I said yesterday, and I will say it again, is I am not a principal to vote on the bill. I am not a member of the legislative body, I am a member of the executive branch.

Dr. BURGESS. You are the primary adviser to the President of the United States on health care policy, you were confirmed by the Senate. It is your obligation to be a principal in these discussions.



Mr. PALLONE. The gentleman's time has expired. The gentleman has expressed his opinion, we have to move on.

Next is the gentleman from North Carolina, Mr. Butterfield.

Mr. BUTTERFIELD. Thank you very much, Mr. Chairman. Let me start by thanking you for being here today. I know it has been a long afternoon for you, but thank you very much for your patience.

Let me also thank you for your leadership throughout this whole health care reform debate. I happen to believe that you have been an integral part of this debate and you have played a very valuable role in this debate. And even though my friend from the other side of the aisle may feel that you were not at the table, I believe that you were. So thank you for your leadership.

Madam Secretary, I am particularly interested in the area of health IT and the investments made in the Office of the National Coordinator of Health IT. Your testimony makes mention of the administration's plan to encourage the adoption of electronic health records through Medicare and Medicaid incentive payments, as provided in the recovery bill. I think this should be applauded, and I appreciate the leadership the administration has shown on the issue.

I must express some concern, however, with the proposed rule issued by CMS on the definition of meaningful use of EHRs, particularly regarding the requirements for hospitals and doctors to receive the incentive payments. How will rural hospitals, including critical access hospitals, be able to meet these objectives? I happen to be from a low-income district, and you and I have had that conversation many times. I represent a very low-income district with major chronic health issues prevalent among constituents. How will those hospitals that serve low-income communities have the resources to meet these objectives? Can you help me with this?

Secretary SEBELIUS. Certainly, Congressman. I think, as you know, that Congress anticipated the Office of Technology would develop a definition for "meaningful use," it is part of the legislative mandate, it is part of the law moving forward. There is an assumption that small providers, small critical care hospitals, those who are not necessarily as technologically savvy right now, haven't started this process, may need more assistance, which is why I think wisely the legislation also anticipates these regional extension centers which will be available. And their primary charge is to focus on underserved areas, to focus on more reduced poverty populations, on hospitals and providers who need additional assistance. So that is part of the framework that is moving forward. So there will be financial incentives, but more than that, there will be actual practical help resource centers, kind of hands-on assistance.

Mr. BUTTERFIELD. But it is not only the small hospitals, it is the medium-size hospitals as well; they just don't have the resources to meet these objectives.

Secretary SEBELIUS. That is right. Well, the resources will be part of the incentives as the bill moves forward. As quickly as people are ready to become part of meaningful users again with assistance and help and support, they will be able to qualify for the payments that Congress allocated in the measure.

Mr. BUTTERFIELD. Let me conclude by thanking you for your support for community health centers. That is a big deal in rural com-

munities as you well know. You have been very sensitive to our needs. This administration has been sensitive. And the President's budget speaks to increased community health centers. The bill that we reported out of this committee was very strong on community health centers. And I just want to thank you and urge you to continue to support the concept of community health centers. They are very valuable in low-income communities.

Thank you. I yield back.

Mr. PALLONE. I thank the gentleman.

And next is the gentleman from Georgia, Mr. Gingrey.

Mr. GINGREY. Mr. Chairman, thank you. Madam Secretary, thank you for your patience and staying with us.

We have an entitlement crisis on our hands. And the unfunded liability, as you know, Madam Secretary, for Medicare alone is \$35 trillion by the year 2075, \$35 trillion. If left unaddressed, this obligation alone could ruin our future economy. Yet in the President's budget, this \$3.8 trillion budget request, I don't see any concrete proposals to improve the Medicare solvency outside the \$251 million that you mentioned in your budget increase to fight waste, fraud and abuse. Surely there are more initiatives available. They certainly are needed to strengthen the Medicare program for our seniors. Why are there no other initiatives included in the budget request so that we can extend the Medicare solvency?

Secretary SEBELIUS. Well, Congressman, again, the budget was put together as a companion piece to a number of the features in health reform, and we hope to be able to move forward aggressively in both fronts.

Moving toward more of a coordinated care strategy on bundled payments, which is a way to actually ensure that we can do everything from reducing the return of one out of every five Medicare patients to the hospital and keep folks not only healthier, but at home, working on hospital-based infections which not only kill 100,000 Americans every year, but actually cost hundreds of millions of dollars year in and year out, those strategies are very much a part of the look forward. We are beginning to focus more of the payment on primary care and general practitioners recognizing that keeping people well at the front end—

Mr. GINGREY. Madam Secretary, I am going to interrupt you. I have a couple more questions I want to ask. I agree with you on that point, certainly wellness is the way to go rather than waiting until people get sick. I certainly don't disagree with you on that as a physician member.

The mandatory part of our budget is probably 60 percent of our spending, and yet in the President's budget there is some shifting of some of the discretionary spending, particularly on the money that was going to be given to the States to help create these high-risk pools—I think something like \$55 million—and make that mandatory spending. It makes it easy, of course, to freeze discretionary and fulfill his pledge to do that over a 3-year period, but it seems to me it is pretty irresponsible to create additional mandatory spending of any amount at a time when we are suffering so badly with these \$1.6 trillion deficits as far as the eye can see.

Would you agree with me that creating additional mandatory spending is certainly not in our best interests?

Secretary SEBELIUS. Well, I think any additional mandatory spending needs to be looked at very carefully. I would certainly agree with that.

Mr. GINGREY. Well, thank you, Madam Secretary. I appreciate that response.

Let me ask you one quick last question. You know from previous times that you have been with us I have always had some concern over the amount of money that we spent on H1N1 and where that money goes and what we do with the amount that is left over, and indeed what we do with the vaccine that is not used. Under the CDC portion of the budget I see there are \$225 million listed as balances from the pandemic flu fund that was passed in June.

Just to be clear, how much of the original \$7.7 billion that was given to the President in June to combat H1N1 virus remains? How much of that money has been unspent at this point?

Secretary SEBELIUS. Congressman, I don't want to give you an incomplete answer. What I would very much like to do is give you a very thorough breakdown of where exactly the money has been spent and where it is. I know that a portion of the supplemental funding, that 209 supplemental funding that was designed to deal with the H1N1—

Mr. GINGREY. Madam Secretary, fair enough. If you would give me—I know you don't have time now, and I want to ask you one last thing, but if I would give me a report back on that, I would very much appreciate if you would get back to me in a timely fashion.

Secretary SEBELIUS. I would be glad to do that.

Mr. GINGREY. The last thing real quickly. In regard to the stockpile of H1N1, how many people have we actually reached that have been vaccinated? And of the remaining stockpile, what percentage actually of the stockpile remains, what happens with that next year? Can we utilize that in any effective way or do we have to discard it?

Secretary SEBELIUS. Congressman, my last numbers from CDC I think were in the 64–65 million range in terms of people who have been vaccinated. States are continuing to order vaccine, as you know. Just at the first of the year the vaccine opportunities opened up, so seniors are beginning to be vaccinated, populations who weren't in the high-risk pool are being vaccinated. And what is happening is that the bulk antigen is absolutely able to be used for future vaccinations. The fill and finish has a more limited time period, so there has been an attempt not to fill and finish every amount of the bulk antigen that has been purchased, and that is being looked at. But the States are continuing to order vaccine, and so we are looking at that issue very carefully.

Mr. GINGREY. Madam Secretary, thank you. Thank you for your patience.

I yield back.

Mr. PALLONE. I thank the gentleman.

The gentlewoman from Florida, Ms. Castor.

Ms. CASTOR. Thank you, Mr. Chairman. And welcome, Madam Secretary.

The collective cheer you heard from Florida families and hospitals last Friday afternoon was the result of your effort to work

with us on a 1115 Medicaid waiver, an amendment to that. I want to thank you very much, and Sydney Mann and Bridgett Taylor and your entire team for helping us get that done.

And then you came to our aid again this week because HHS rightfully activated the National Disaster Medical System because after the January 12 earthquake in Haiti, hundreds of evacuees have come to the State of Florida for medical care and treatment that is not available in Haiti. In fact, the State of Florida has treated 618 people from Haiti who were injured in the earthquake. Many are still in our hospitals receiving treatment, and that National Disaster Medical System is helping evacuate Americans and Haitians, and we really appreciate it.

Here is my question: How long will it remain activated?

Secretary SEBELIUS. I think, Congresswoman, that is a question that we are not quite sure that we can answer right now. What was clear in the conversations with your Governor and other State officials like yourself is that the disproportionate brunt that Florida was bearing did not seem appropriate when there was really a national and international response to the crisis.

The effort is to stand up medical care in Haiti as quickly as possible. A number of the people being evacuated right now are actually doing post-op care. They have surgical treatment on the USNS Comfort and then need to be brought somewhere for care. That, hopefully, will be available in Haiti in the very near future. There is a 325 bed hospital that should be up and running within days, literally, that can be expanded to 1,000 beds, doctors and medical supplies being gathered. So the government of Haiti, and others, would far prefer, frankly, that we help build those assets in Haiti, and that is what really the international community is responding to. So this is a stopgap, but I can't tell you exactly how long.

Ms. CASTOR. So we will continue to have a dialogue on that.

And Florida's Department of Children and Families has begun repatriation efforts for more than 25 Haitians following the earthquake. Under the current law, Haitians who are granted temporary protective status are considered Cuban Haitian entrants and they are, therefore, eligible for medical Federal assistance such as Medicaid for 7 years after they arrive in the United States. Consequently, Florida, and I am sure other States, will have a sizeable number of newly Medicaid-eligible residents for years to come. Does the administration's budget consider this? I know that the budget probably was mostly put together before this time, so does it consider this?

Secretary SEBELIUS. No. The budget really was put together before the earthquake hit, and so we are having conversations not only in our agency, but government-wide, about what this assistance needs to encompass.

Ms. CASTOR. So you will continue to work with us—

Secretary SEBELIUS. Your Office of Children and Families has been absolutely spectacular.

Ms. CASTOR. Well, I appreciate that, and I will pass that on to the Secretary.

Will this be handled through FMAP or some other means? Or we will have that dialogue going forward.

Secretary SEBELIUS. Currently, Congresswoman, there are lots of alternatives. Our Office of Refugee Assistance is one, there are other avenues, but those conversations are really underway.

Ms. CASTOR. OK. In a somewhat related vein, there are many States that are prone to natural disasters. For example, in Florida, in recent years we were hit by seven hurricanes, and it skewed our FMAP calculation because after the hurricanes we had a huge run-up of reconstruction and jobs so that when the recession hit, the formula really hurt us, we didn't have the money coming in under FMAP. Now, fortunately through the Recovery Act we have made some of that up. But I would like to look at a permanent solution for States that run into these kind of problems so that at the worst time we are not penalized just because of a post-disaster run-up in employment.

Would you work with me on that type of solution, or do you have any recommendations at this time on how to—

Secretary SEBELIUS. No, I think that is a very real issue and problem that is not unique to Florida. It has been experienced by a number of States, and I think there are also a number of Members who think that the entire FMAP formula needs to be revisited. So this could be one aspect of that.

Ms. CASTOR. Thank you very much.

Mr. PALLONE. The gentlewoman's time is expired.

The gentleman from Maryland, Mr. Sarbanes.

Mr. SARBANES. I know you are delighted to see me because I am the last one to ask you questions.

Secretary SEBELIUS. Always delighted to see you, Congressman.

Mr. SARBANES. Thank you.

First of all, I want to commend you on your remarkable composure, which I judge as remarkable because if I had to sit where you are sitting and bear some of the hectoring that you did today, I don't think I would have been able to exhibit the same composure. And you don't have to respond to that.

I do want to say that I think you are doing a wonderful job in your position. And you have a bearing which I think will stand the agency in good stead and has been very effective in dealing with the public on all manner of issues, including the H1N1 flu virus, and others. We are really blessed to have you there.

It cannot have been easy to put this budget together given what a moving target the health reform bill has been. And regardless of what happens with that reform effort, your work will remain really at the center of the health system, and particularly the public health system. So I thank you for the work you are doing. You have clearly put together a tremendous staff that I know is working around the clock on these issues.

There are so many good things that are in those health reform bills, and many of them are ones that your budget reflects as well. I just wanted to point to a couple of them and ask a couple of questions.

First of all, there is a discussion of these Medicare demonstration projects and some other initiatives to determine how to better align provider payments with the kinds of outcomes and treatments and regimens that we want to see. I have been long fascinated by the, I think, overemphasis on procedure reimbursement versus time

spent with patients. I am wondering if you could just speak to whether some of these demonstration projects are intended to determine how we can enhance outcomes and treatment approaches if we look to providing better reimbursement so that physicians can be rewarded for spending a little extra time with their patients.

Secretary SEBELIUS. Well, I think that is certainly one of the outcomes that would be most desirable, not only providing financial incentives to spend more time, but certainly the kind of coordinated care strategies which we know work well with not just physicians, but sort of medical teams that, following a patient's release from a hospital, can be much more effective at keeping that patient well and healthy and on a pathway to success. So we have added Medicare to a demonstration project that is going on in the Northeast, which we think can be a great success.

We know that too often physicians—and, Dr. Gingrey, you may have this experience—talk about not being able to see people on a regular basis to keep them well, but they get the incentives tilt toward sick care and not health care. So I think we have got a great deal of opportunity to move into that preventative care, wellness strategy space with financial incentives and other strategies to make sure that providers can be providers.

Mr. SARBANES. Great. I wanted to congratulate you on the resources going towards the National Health Service Corps, enhancing the number of primary care providers out there, and other initiatives which include as a component of helping students with the debt burden that they carry—that is something that I am particularly focused on across the board and authored a provision that actually the President mentioned the other day relating to loan forgiveness for those who go into public service. So I really encourage that effort.

The last thing I will just mention, because I am running out of time, is I am very interested as well in this idea of what I call place-based health care, which is to think about instead of relying on the patient to come to our health care system, we think about how we can bring the system to the patient, and think about where people are already gathered, where there is a captive audience. The most obvious example of this is schools. I would love to continue to work with your office on all things school-based when it comes to health initiatives because I think there is tremendous opportunity there to provide screening and preventive services and other things, potentially even help with the enrollment around CHIP, although I know that is something that has to be worked through perhaps on a State-by-State basis, but there is tremendous potential there. And you know that the H1N1 outbreak in New York City, for example, was spotted by a school nurse. There is so much more we can do to enhance the public health infrastructure of the country if we focus in on these places where people already are. So I look forward to continued efforts in that regard as well.

Secretary SEBELIUS. Well, Congressman, I think not only is your effort in that area appreciated, but one of the great success stories of H1N1 will be the school-base vaccination clinics, where schools really were great partners. They were even better when there was a school-based health clinic that was then reaching out to the parents and grandparents and younger siblings of those children.

I can tell you that the new Secretary of Education and I have already had discussions about how we can accelerate and encourage more school-based health clinics because I agree with you, it is a great way to provide cost-effective health care and reach folks where they are comfortable and coming on a regular basis. Unfortunately, the number of school-based health clinics is kind of frozen. It was a large investment, and then it has kind of flattened out. But I think the way community health centers have become part of the infrastructure, I think school-based health clinics also need to be looked at as one of the ways to expand access site and deliver low-cost, high-quality preventative care not only to children, but to their parents and grandparents, to the neighborhoods around the schools and have the schools be a health center.

Mr. PALLONE. Thank you, Madam Secretary.

Mr. SHIMKUS. Mr. Chairman, I ask unanimous consent for a second round of questions.

Ms. CASTOR. Objection.

Mr. SHIMKUS. Is the gentlewoman from Florida the one who objected? I am just trying to identify which person objected in the front row. Is it the gentlelady from Florida?

Mr. PALLONE. She did object.

Mr. SHIMKUS. Objected to a second round of questions of the Secretary? I would like to thank her.

Mr. Chairman, point of order.

Mr. PALLONE. Let me just respond to you.

The chairman, Chairman Waxman, made it very clear from the beginning that what we were doing is having everyone have 5 minutes to either ask questions or make a comment, or whatever. It was quite clear that we were not having a second round and that that is what we were doing today. So I am not going to proceed to a second round because I think it was quite clear from the beginning that that is not what we were doing.

Mr. SHIMKUS. A unanimous consent request, Mr. Chairman. Just for anyone who has questions to be able to submit them to the Secretary.

Mr. PALLONE. Yes, absolutely.

Mr. SHIMKUS. I don't know if that question was made prior.

Mr. PALLONE. I know you have some written questions you would like to submit to the Secretary, I know others will, so we will allow—I mean, we always do, but I will specifically say today that we will have some written questions, and we would like you to get back to us in a timely fashion, Madam Secretary.

Mr. SHIMKUS. Mr. Chairman, will there be a time limit that we expect these responses to be made? As we saw, some came quick, quite a few came long.

Mr. PALLONE. I believe that, generally speaking—but I don't want to put you in any kind of a straitjacket here—but generally speaking, we ask the Members to submit those questions within 10 days, I believe. And I would ask that for whatever you get within those 10 days, that you get back to us in a reasonable time, a few weeks.

Mr. SHIMKUS. Mr. Chairman, is this the last time we will see the Secretary this year before this committee?

Mr. PALLONE. I certainly hope not. I have thoroughly enjoyed seeing her.

Mr. SHIMKUS. Part of the frustration is we have the head of one of the largest departments in the Federal Government and we have 3 hours with her.

Mr. PALLONE. I understand.

Mr. SHIMKUS. With the major policy decisions that health care has been, with a promise that she would have been here after the rollout of the bill, which never occurred. So that is our frustration, and we would like to have more time.

Mr. PALLONE. Well, we are not doing it today. We will see if there is another opportunity, but I don't want to make any commitments at this time.

But I do want to thank you for being here today. I know it was suggested that it was tough; it wasn't really that tough compared to some of our meetings. But we do appreciate all that you have done really, not only on health reform, but also on all the different health issues that come before your Department. Thanks so much.

Without objection, this committee is adjourned.

[Whereupon, at 5:20 p.m., the committee was adjourned.]

[Material submitted for inclusion in the record follows:]



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 STEVE SCALISE, LOUISIANA

The Honorable Kathleen Sebelius  
 Secretary  
 Department of Health and Human Services  
 200 Independence Avenue, S.W.  
 Washington, D.C. 20201

Dear Secretary Sebelius:

We write to request information from the Department of Health and Human Services (HHS) relating to the Environmental Protection Agency (EPA) use of HHS special pay authorities under Title 42, particularly 42 U.S.C. §209(f) related to the appointment of "special consultants." Section 209(f) provides: "In accordance with regulations, special consultants may be employed to assist and advise in the operations of the [Public Health] service. Such consultants may be appointed without regard to the civil-service laws." HHS uses 209(f) as a recruiting or retention tool to pay HHS scientific employees much higher salaries than the salaries these employees could get under federal Civil Service systems.

We have learned that the EPA is using HHS special pay authorities for EPA employees. In its commentary for the implementing regulation, EPA claimed it acquired Title 42 pay authorities from The Interior, Environment, and Related Agencies Appropriations Act of 2006 (Public Law 109-54). That act included language that the EPA could appoint up to five research fellows "to the Office of Research and Development" in any fiscal year through fiscal year 2011. We note the Administration's Budget for FY 2010 requested employment of up to 30 persons at any one time in the EPA's Office of Research and Development under the authority provided in 42 U.S.C. §209, and that this provision was enacted as part of the Omnibus Appropriations Act of 2009, Public Law 111-8. Further, the Department of the Interior, Environment, and Related Agencies Appropriations Act of 2010 (H.R. 2996) as passed by the House on June 26, 2009, included a provision extending the Title 42 program at EPA through fiscal year 2015.

Letter to the Honorable Kathleen Sebelius  
Page 2

There is reason to believe that EPA is using the research fellow program as a way to expand 209(f) authority into a comprehensive pay system similar to the HHS Title 42 program. In the summary for the direct final rule issued on April 4, 2006, EPA stated that the agency was taking direct final action on the implementation of statutory authority in the 2006 Appropriations Act “that will allow the EPA to establish fellowships in environmental protection research, appoint fellows to conduct this research, *and appoint special research consultants to advise on environmental protection research.*” (Emphasis added.) EPA regulation 40 C.F.R. §18.10 authorizes the appointment of special research consultants for environmental protection “to assist and advise in the operations of the EPA” in addition to these fellowship appointments established by 40 C.F.R. §18.2. The EPA Order 3110.22 on “Title 42 Special Hiring Authority – Policy, Responsibilities, Requirements” (September 19, 2006) specifically cites 42 U.S.C. §209(f)-(g) as authorities. Although Title 42 appointments are limited to EPA’s Office of Research and Development, we note that EPA has established a comprehensive set of policies and tools to govern the implementation of the authority, including a Title 42 Operations Manual and various forms and worksheets. One of the forms is a template that can be used by EPA employees seeking voluntary conversion to a Title 42 position (see attachment). EPA has also established a pay range. The bottom of the range is defined as the maximum pay rate of the tenth step for a GS-15 (including locality pay) and the top annual pay is currently \$250,000, with total annual compensation for a Title 42 position up to \$275,000.

EPA is an independent agency, not part of HHS or the Public Health Service. While the Appropriations Act referenced the statutory authority of 42 U.S.C. §209 with respect to EPA appointments to the EPA Office of Research and Development, the language of the underlying statute 42 U.S.C. §209 was not amended to extend coverage to the EPA. We are curious how EPA can legally use statutory authority explicitly committed to the Public Health Service and the Surgeon General, particularly the special consultant authority in 209(f), and whether HHS has made any kind of interpretation of its statutory authority of 42 U.S.C. §209 that would relate in any way to EPA.

It is understandable why EPA would desire the HHS Title 42 pay authorities. Over the last decade, HHS and three of its Public Health Service agencies have expanded the use of 209(f) special consultants to convert individuals from continuing, full-time federal positions into special consultants to perform the same official duties but at much higher salaries. According to HHS data provided to the Minority Committee staff in August 2008, since 1999, 1,246 employees have been converted from the federal Civil Service to 209(f) status. Due to these conversions, HHS spent \$19,064,942 in increased salaries, an average increase in annual salary of \$15,301 per conversion. Further, since January 1, 1999, 1,858 individuals have been hired directly under 209(f). As mentioned previously, the salaries of many of these individuals are far greater than would be paid under the General Schedule. For example, as of August 2008, HHS was paying 378 individuals annual salaries above Executive Level 1 (\$191,000), with 323 at the National Institutes of Health (NIH), 19 at the Food and Drug Administration (FDA), 35 at the Centers for Disease Control and Prevention (CDC), and one at the Office of the Secretary (OS).

Letter to the Honorable Kathleen Sebelius  
Page 3

Most senior scientific officials at NIH, FDA, and the CDC earn salaries well in excess of the salary of the Vice President. For example, according to publicly available 2008 Office of Personnel Management data, at least seven Institute Directors at the NIH received \$300,000 or more in base salary, up to \$335,000 in annual salary. One of the justifications for HHS expanding 209(f) authority was to facilitate the Department's ability to retain scientists through higher 209(f) salaries that would not otherwise be possible due to Civil Service compensation restrictions.

In addition, individuals receiving 209(f) salaries can also get retention bonuses. As of August 2008, HHS reported to Minority Committee staff that HHS and HHS agencies had paid \$6,392,683.49 since 1999 in retention bonuses to individuals getting 209(f) pay (208 retention bonuses affecting 76 employees - an average of \$30,845 per bonus).

In light of our concerns over use by EPA of HHS authority under 42 U.S.C. §209, we respectfully request HHS to provide technical assistance in the interpretation of its statute and that responses in writing to the following questions be provided within two weeks of the date of this letter:

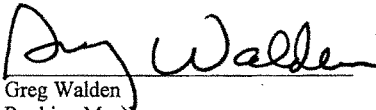
1. Is the EPA part of the Public Health Service? Does the meaning of "Surgeon General" in 42 U.S.C. §209(g) include the Administrator of the EPA? What agencies outside of HHS are included in the definition of the "Public Health Service" and/or have 209(f) or (g) authority? How are such determinations made? Since EPA states it is relying on HHS statutory authority under 42 U.S.C. §209, must EPA in turn rely on HHS' administration of the provision or can EPA issue its own implementing regulations?
2. If the Title 42 pay authorities can be applied to the EPA, could they be applied to any federal department or agency merely by asserting 42 U.S.C. §209 authority in that department's or agency's appropriations law? As a matter of statutory interpretation, is it correct that 42 U.S.C. §209(f) is not limited in application to scientist employees? As a matter of statutory interpretation, is it correct that there are no salary caps imposed by either 42 U.S.C. §209(f) or 42 U.S.C. §209(g)?
3. Did HHS delegate authority or authorize the EPA to appoint and compensate individuals under 42 U.S.C. §209(f) and/or 42 U.S.C. §209(g)? If HHS did delegate this authority to EPA, what is the legal basis of this delegation?
4. Did HHS (including any HHS agencies) provide any kind of assistance to EPA related to special pay authorities under 42 U.S.C. §209? If so, please explain in detail the nature of the assistance, the dates such assistance was provided, and the names and titles of the officials who provided such assistance. Did any of this assistance involve any legislation related to special pay authorities under 42 U.S.C. §209?

Letter to the Honorable Kathleen Sebelius  
Page 4

We appreciate your attention to this important issue. Please do not hesitate to contact the Minority Committee staff at (202) 225-3641 if you have any questions about this matter.

Sincerely,

  
\_\_\_\_\_  
Joe Barton  
Ranking Member

  
\_\_\_\_\_  
Greg Walden  
Ranking Member  
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Chairman  
  
The Honorable Bart Stupak, Chairman  
Subcommittee on Oversight and Investigations

**TITLE 42 VOLUNTARY CONVERSIONS AND EMPLOYMENT NOTICE**

I, *(employee name)*, voluntarily request the conversion from my current civil service position under Title 5 U.S.C. to a position under Title 42, Sections 209(f) or 209(g), within the Environmental Protection Agency, Office of Research and Development, *(Laboratory/Center/Office name)*.

Specifically, I understand that I am converting from my current position of *(position title, series, grade, step)*, with an annual salary of *(salary)* to the position of *(position title, series)*, with an annual salary of *(Title 42 salary)*. I understand that I will be assigned to a position description for the position I am accepting.

I understand that the Title 42 appointment does not represent a permanent position within the Federal service. I understand that this appointment is for *(time period)* and may be extended in one to five-year increments, subject to appropriate reviews and approval.

I understand that as a Title 42 employee, I will be placed on a performance plan appropriate for my position. I understand that my performance will be formally reviewed at least twice a year.

I understand that pay increases will be determined by, among other things, my performance, the Title 42 total compensation ceiling, and the availability of funds. I further understand that the Title 42 appointment may be terminated prior to the expiration date of the appointment for any lawful reason.

I understand that as a Title 42 employee, I will retain any reinstatement eligibility to which I am currently entitled. If I wish to return to the civil service under Title 5 in the future, I understand that I must apply and be selected for the position.

I hereby acknowledge and accept the terms and conditions above:

---

Employee Name

---

Date

**Congress of the United States**  
 Washington, DC 20510

February 3, 2010

The Honorable Kathleen Sebelius  
 Secretary  
 U.S. Department of Health & Human Services  
 200 Independence Avenue, S.W.  
 Washington, D.C. 20201

Dear Secretary Sebelius;

We are requesting the Department of Health and Human Services, through the Office of Refugee Resettlement (ORR), to provide additional financial assistance to school districts that are currently seeing an influx of Haitian refugees, Haitian immigrants and Haitian-Americans returning to the U.S. after the recent earthquake. Due to these unique circumstances, there is a need for immediate emergency funding for local school districts, and a funding increase to the School Impact grant program, above the \$15 million allocated in the Administration for Children and Families FY11 Congressional Justification.

As you are aware, the earthquake on January 12, 2010 devastated the country of Haiti. Over one hundred thousand have been confirmed killed, countless buildings have been destroyed, and families torn apart. The conditions in Haiti have made it impossible for Haitians to return to their home country, prompting U.S. Secretary of Homeland Security Secretary Napolitano to respond to our request and grant Temporary Protected Status (TPS) for those already in the U.S. Along with the large number of Haitians who will remain here under TPS, many Haitian-Americans are returning to the U.S., as well as Haitian-Americans trying to bring minor children to the U.S. who may not have family left to take care of them in Haiti. In the coming weeks and months, there is an expectation that a great number of refugees will arrive in the U.S., many who will relocate near friends and family in New York. It is our responsibility to assist our local school districts to educate these newly arrived refugees, and provide them with the proper resources so they may fully integrate into our society.

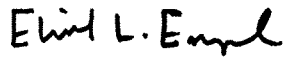
As the Congressman and Senator representing a large concentration of Haitians and Haitian-Americans, local school district superintendents in Rockland County have already made clear the need for additional financial assistance required at this time. In addition to the Refugee School Impact grant program currently offered by ORR, there is a strong need for an emergency grant program for local school districts outside of the limited Refugee School Impact grant program, which uses a two year project cycle and backward looking refugee data. It is shocking to note that during FY10, FY09, FY08, and FY07 the funding for the Refugee School Impact grant program has not increased over \$15 million. Within the Administration for Children and Families FY11 Congressional Justification, a request is made again for only \$15 million for this grant program. However, an additional \$25 million was allocated for Social Service grant

programs to assist Emerging Populations programs, which does not include assistance for school districts. We support fully funding President Obama's FY11 budget request to fund the Social Services programs of the ORR at \$253 million, an increase of \$25 million above FY10. However, we strongly encourage you to use some of this additional funding to implement a one time emergency grant program for the most heavily affected school districts and increase the funding above \$15 million Refugee School Impact grant program.

In today's tough economic times, the vital services provided by local school districts to refugees will be stretched even thinner without additional financial support from the Office of Refugee Resettlement, particularly through the Refugee School Impact grant program.

As members of the House Foreign Affairs and Senate Foreign Relations Committees and Congressman Engel as senior member of the Energy & Commerce Health Subcommittee, we would like to thank you for the assistance that you are already providing to states, localities, and school districts in providing needed resources for newly arrived refugee populations. We look forward to working with you in providing additional financial resources to assist our local school districts and communities with the resettlement of Haitian refugees.

Sincerely,



Eliot L. Engel  
Member of Congress



Kirsten Gillibrand  
United States Senator

cc. Director Eskinder Negash, Office of Refugee Resettlement

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# Congress of the United States

## House of Representatives

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March 1, 2010

The Honorable Kathleen Sebelius  
Secretary  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Madam Secretary:

Thank you for appearing before the Committee on Energy and Commerce on February 4, 2010, at the hearing regarding the President's Fiscal Year 2011 Budget for the Department of Health and Human Services.

Pursuant to the Committee's Rules, attached are written questions for the record directed to you from certain Members of the Committee. In preparing your answers, please address your response to the Member who submitted the questions.

Please provide your responses by March 17, 2010, to Earley Green, Chief Clerk, in Room 2125 of the Rayburn House Office Building and via e-mail to [Earley.Green@mail.house.gov](mailto:Earley.Green@mail.house.gov). Please contact Earley Green or Jennifer Berenholz at (202) 225-2927 if you have any questions.

Sincerely,



Henry A. Waxman  
Chairman

Attachment



**The Honorable Bobby L. Rush**

- 1. Madame Secretary, I do notice some substantial increases in the proposed budget in certain key areas that serve low-income populations and communities. I would like to learn more about how increases in priority spending in the budget addresses childhood obesity, funding for community health centers, and minority healthcare disparities.**

Improving health outcomes for Americans through a broad-range of programs and targeted efforts including, reduction of childhood obesity, improving access to high quality care through community health centers, and eliminating racial and ethnic minority health and healthcare disparities is a priority for the Department of Health and Human Services.

**Childhood Obesity**

The President's 2011 Budget Request for the Centers for Disease Control and Prevention includes increases for two programs that help address childhood obesity.

First, the President's request includes \$61,520,000 for School Health in FY 2011, an increase of \$3,875,000 above the FY 2010 Omnibus. With the additional funding, CDC will support local education agencies through training and technical assistance to assure continued coordination of efforts with state health departments. This investment will increase CDC's ability to reach more children and youth through quality school health programs.

This funding will support efforts to combat childhood obesity by focusing on strategies aimed at:

- Increasing the number of school districts that prohibit junk foods in vending machines, school stores, canteens, or snack bars;
- Increasing the number of states with policies to improve nutritional quality of competitive foods in schools;
- Increasing the percentage of high school students who attend physical education class daily;
- Increasing the number of states that have multi-component policies that support quality physical education;
- Increasing the number of states that require elementary schools to provide students with regularly scheduled recess; and
- Increasing the number of schools that have policies prohibiting tobacco use on school property.

Second, the President's 2011 Budget also includes a request for \$20 million to fund up to 10 cities with populations over 1.5 million people, to implement evidence-based programs targeting three public health priorities – obesity prevention and control, tobacco

prevention and control; and chronic disease detection and management. The initiative will impact childhood obesity through the following key elements:

- Promoting healthy communities through policy, environmental, and systems changes that support people to be more physically active, eat a healthy diet, and maintain a healthy weight. Examples of interventions that would impact childhood obesity include:
  - Improving access through reduced-cost fruits and vegetables; and
  - Changing the local infrastructure to support walking and bicycling.
- Promoting healthy schools that enable students through policies, curricula, and health services, to be physically active, eat a healthy diet, and maintain a normal weight. Examples of interventions that would impact childhood obesity include:
  - Strengthening school-based physical education;
  - Increasing opportunities for students to engage in physical activity; and
  - Ensuring student access to healthy food and beverage choices.

#### **Community Health Centers**

The FY 2011 Budget Request also includes \$2.479 billion for the Health Center Program, an increase of \$289 million over the FY 2010 Appropriation. The request includes \$249 million to continue providing services to an estimated 2.1 million health center patients served under the Recovery Act, 1 million of which are uninsured. This funding level will support the development of approximately 25 new access points, expanding access to primary health care services to an estimated 150,000 additional health center patients. The requested increase also includes \$25 million for substance abuse/behavioral health grants. Overall, the increase in the Health Center Program funding level will support the goal of increasing access to care for our Nation's most vulnerable populations and the medically underserved.

#### **Minority Health and Health Disparities**

The President's FY 2011 Budget request for the Office of Minority Health (OMH) is \$58 million, which represents an increase of \$2 million. This funding includes support for demonstration programs that support community-level strategies to engage racial and ethnic minorities in health care and ultimately reduce health disparities, a national campaign called "A Healthy Baby Begins with You" that targets elimination of health disparities in infant mortality among African Americans in particular, and implementation of a National Plan for Action to end health disparities. This National Plan for Action is near completion and I look forward to sharing more information about this plan in the coming weeks.

2. **I am concerned about the very modest increase to the Office of Minority Health of only \$2 million. Can you discuss any reasons why this particular office did not see as much improvement in the budget in relation to the large focus placed on eliminating health disparities during the current healthcare reform process?**

There has been no lack of focus or attention or interest in closing the gap in health disparities, which continue to be alarming and appalling. The new Assistant Secretary of Health, Dr. Howard Koh, also takes the issue of disparities very seriously. The Office of Minority Health (OMH), formerly located within the Office of Public Health and Science, has been funded through the General Departmental Management (GDM) appropriation.

The just-enacted Patient Protection and Affordable Care Act (PPACA) relocates OMH in the Office of the Secretary, with the Deputy Assistant Secretary for Minority Health reporting directly to the Secretary. In addition, the PPACA establishes Offices of Minority Health in six HHS agencies (CDC, HRSA, SAMHSA, AHRQ, FDA and CMS). The Secretary must designate funds for those offices out of the appropriated funds for each agency for carrying out the activities of each agency Office of Minority Health.

OMH is leading the development and implementation of the National Plan for Action which focuses on the increased awareness of the significance of health disparities, their impact on the nation, and the actions necessary to improve health outcomes. In addition, among the programs and activities funded in GDM, the OMH request is a 3.5 percent increase over FY 2010, while the requests for much of the organization are either level-funded or a decrease for FY 2011.

Additionally, through the leadership of the National Center for Minority Health and Health Disparities, the National Institutes of Health (NIH) continues to advance minority health and the elimination of health disparities, thereby improving health outcomes and prolonging lives. The President's FY2011 Budget request for the NCMHD is \$219 million, an increase of \$8 million. The NCMHD leadership assures effective trans-NIH coordination of biomedical and behavioral research activities to address the diseases and conditions that disproportionately impact minority health and other health disparity populations. In their own right, NCMHD's research programs have focused on cutting edge translational and trans-disciplinary research that links the biological and non-biological determinants of health and have led to discoveries that have contributed significantly to the understanding of racial and ethnic differences in disease conditions.

**The Honorable Lois Capps**

**Global Health**

**In your testimony, you noted that global health programs, including those that address maternal and child health, will receive an increase of 16 million dollars. The budget also includes several ambitious targets to be reached by 2014, including reducing maternal mortality by 30%. However, even in these modern times, women in the U.S. continue to die during pregnancy or childbirth.**

- 1. Can you discuss any efforts being made domestically to reduce our maternal mortality numbers and can you also mention any efforts to address disparities among different racial and ethnic groups?**

The rate of maternal deaths in the U.S. is a concern that the Department of Health and Human Services takes very seriously. The Maternal and Child Health (MCH) block grant, administered by HRSA, provides access to comprehensive prenatal and postnatal care for women. The grant also supports federal and state partnerships that provide maternal health services to more than 2.6 million women. HHS also provides funding through the Healthy Start Program, which provides services tailored to the needs of high-risk pregnant women, infants and mothers in geographically, racially, ethnically and linguistically diverse low-income communities. The Healthy Start program helps ensure that pregnant women have ongoing sources of primary and preventive healthcare and that their basic needs are met. Pregnant women are linked to a medical home and followed, at a minimum, from entry into prenatal care through two years after delivery.

The Centers for Disease Control and Prevention also play an important role in HHS' work in this area. The cornerstone of CDC's efforts to understand and reduce maternal mortality is surveillance. The Pregnancy Mortality Surveillance System (PMSS) is CDC's primary surveillance system to better understand the number, racial and ethnic health disparities, and geographic spread of deaths related to pregnancy in the United States. The PMSS is a collaboration between CDC and states' Divisions of Vital Statistics. Medical epidemiologists inspect all of the information found on death, birth, and fetal death certificates to make a reasoned medical decision about the cause and timing of death, the outcome of the involved pregnancy and the relationship of the woman's death to her pregnancy.

Regarding applied public health research, CDC is building maternal and child health (MCH) epidemiology and data capacity at the state, local, and tribal levels to effectively use epidemiologic research and scientific information to improve the health of women, children, and families. The MCH-EPI program design allows for expertise and assistance with priority projects such as: maternal and infant mortality and morbidity, flu preparedness, and tobacco cessation in pregnant women. The budget request for FY

2011, will support 14 MCH assignees in states. In addition, CDC epidemiologists will continue to provide technical assistance to all states including state maternal mortality review committees.

CDC is working with professional healthcare organizations, such as the American Congress of Obstetrics and Gynecology (ACOG), to educate practicing physicians regarding evidence-based interventions to reduce maternal mortality. Work with ACOG also includes highlighting new and emerging issues in maternal health.

In response to the significant disparities in infant mortality and maternal deaths among African American women, the Office of Minority Health launched the “A Healthy Baby Begins with You” campaign. The campaign is a call to action and seeks to educate women, men, family members, health professionals, and others about the significant disparities for African Americans, and engage stakeholders in addressing the problem.

The “A Healthy Baby Begins with You” campaign also has a Preconception Peer Educator Program (PPE) that focuses on maintaining good health throughout a lifetime, but in particular before a woman becomes pregnant. The goals of the PPE program are to:

1. Reach the African-American college-age population with targeted health messages emphasizing preconception health and healthcare.
2. Train minority college students as peer educators.
3. Arm peer educators with evidence-based materials, activities, and education support that assists their efforts to inform peers in college and in the community at large about being healthy.

Tonya Lewis Lee, wife of film-maker Spike Lee, is the National Spokesperson for the campaign which has provided education and contributed to PPE and awareness events all across the country. These efforts are reinforced by OMH demonstration projects within its Community Partnership program that seek community-based approaches to improving health and health outcomes.

#### **Climate Change**

**Climate change is an emerging public health issue. It is expected to worsen many health problems, including weather-related illness and injury, and infectious diseases.**

2. **Secretary Sebelius, what is being done across the Department to prevent and prepare for the health effects of climate change?**

**Many state and local health officials do not believe they currently have the expertise or capacity to address climate change.**

The Department of Health and Human Services is participating in the Interdepartmental Work Group on Climate Change and Health recently established by the U.S. Global Change Research Program. Within HHS, I have designated Assistant Secretary for Health Howard Koh to serve as the Departmental lead on climate change. In this capacity, Dr. Koh has convened an HHS Climate Change and Health Working Group comprised of representatives from the agencies and offices within HHS that have climate change portfolios. This group serves to enhance Departmental communication and collaboration on climate change activities.

The Center for Disease Control and Prevention (CDC) is doing significant work to address the effects of climate change. Congress appropriated \$7.5 million to establish CDC's Climate Change Program in FY 2009. This funding supported pilot projects to conduct needs assessments in five states and six localities to enhance state climate change expertise and capacity, to support workforce development programs, to fund applied research grants, to conduct cross-agency coordination of climate change efforts, and to incorporate climate change into existing agency work. In FY 2010, CDC will improve its support to state and local health departments by using a two-tiered approach:

- 1) Expanding climate change capacity in state and local health departments to identify what the health impacts will be and which populations will be most threatened.
- 2) Expanding support in health departments that know their climate change needs and their vulnerable populations and now need to develop a strategy to protect those communities.

This funding will be made available to 10 to 12 state and local health departments for three years. CDC's assistance will:

- Provide technical assistance, training and decision tools to help state and local health officials conduct needs assessments to inform strategic planning;
- Conduct investigations to better understand the relationship between climate change and adverse human health outcomes;
- Translate surveillance and research on climate-related health impacts into methods and best practices to inform state and local health practitioners; and
- Improve coordination and integration of climate change across CDC.

The National Institutes of Health (NIH) support research on a variety of health outcomes, ranging from heart disease to malaria, which may be affected by changes in climate. In addition, there is a growing portfolio of research focused more specifically on improving our ability to assess the health consequences of climate change. For example, as part of the American Recovery and Reinvestment Act of 2009, NIH funded five research proposals that will model heat morbidity and mortality, respiratory and cardiovascular effects of wildfires, asthma, skin cancer, salmonellosis, cholera, and diseases associated with climate-induced population movement.

Other agencies within HHS are working on this issue as well. The Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration is working to characterize the risks to the food supply in face of changing climate conditions. The Office of the Assistant Secretary for Preparedness and Response (ASPR) works with partners in the Federal and State governments, the private sector, and communities to strengthen the Nation's ability to prepare for, protect against, respond to, and recover from a wide range of catastrophic possibilities, including those that are potentially related to climate change. The Office of Global Health Affairs (OGHA) plays a key role in interacting with multilateral organizations and other countries on the topic of climate change.

**3. How else can the Department and CDC support state and local health officials and provide them with the technical assistance and expertise they need to address the health effects of climate change?**

In addition to all of the programs mentioned above, the CDC will continue to fund state and local health departments to address the impact of climate change, and will continue to invest in workforce development and training programs for state and local officials. I would like to continue working with you and your colleagues in Congress on this issue. Together we can consider ways that current programs could enhance our efforts to address the impacts of climate change, or explore new ideas, such as enhancing applied research to provide state and local officials with the best scientific information on which to base actions and policy.

**Health IT**

I'm very excited by the prospects of widespread Health Information Technology adoption and applaud the increased investment both through the Recovery Act last year and now in this year's budget. But I have heard concerns from some hospitals and physicians about the timeline and requirements for adoption. For example, some of the timeframes for meeting the definition of meaningful use are difficult to achieve before the penalties begin. Further complicating this is the lack of finalized standards put forth by the HIT Coordinator.

**4. Are you aware of the concerns of the medical community regarding how soon requirements for assuring "meaningful use" must be achieved? And what is the Administration doing to work with providers to alleviate their concerns so that they may be eligible for incentive payments sooner?**

The Administration has now issued draft regulations for all three components, including Notices of Proposed Rulemaking (NPRM) for meaningful use and a certification process, and an Interim Final Rule for certification criteria and standards. We believe that this will enable sufficient time for motivated vendors and providers to

achieve Stage I meaningful use in 2011 and 2012.

The meaningful use (MU) requirements have been published in draft through an NPRM, and are currently in a public comment period. Commenters will provide feedback on the requirements and other areas of the program. We will carefully review the comments received and may make adjustments depending on what we hear from the public.

Some providers may need more assistance in meeting the standards that have been set, and Congress wisely anticipated this need by creating the Regional Extension Centers (REC) grants program in the HITECH Act. The regional centers will offer technical assistance, guidance, and information on best practices to support and accelerate health care providers' efforts to become meaningful users of Electronic Health Records (EHRs). The REC program will establish an estimated 70 regional centers, each serving a defined geographic area. The regional centers will support at least 100,000 primary care providers, through participating non-profit organizations, in achieving meaningful use of EHRs and enabling nationwide health information exchange. 32 of the REC grants were awarded in mid-February, and the remaining REC grants were awarded on April 6, 2010.



**The Honorable Tammy Baldwin**

- 1. In terms of your new proposal to create a “Health Prevention Corps,” which includes a focus on laboratory professionals, is there anything Congress needs to do to support you in this area, or can you proceed with this initiative? I see your budget for FY11 allows for a one year planning phase; how long do you expect it will take the CDC to enlist Corps members? How will this new Health Prevention Corps interact with current workforce development and fellowship programs funded by the CDC?**

The Health Prevention Corps (HPC) is a new initiative in the FY 2011 President’s Budget, which will recruit new talent into service in disciplines with known shortages such as epidemiology, environmental health, and laboratory science. CDC is currently assessing whether it has sufficient authority to proceed with this initiative under existing Public Health Service Act authorities.

This proposal is modeled after CDC’s existing, successful fellowship programs and will require a similar level of effort to ensure successful program implementation. The timing of recruitment and placement of the first class of Health Prevention Corps participants will take approximately one year from the receipt of funding for the program.

The majority of CDC’s current fellowship programs are designed for candidates who are studying for or who have completed a master’s or doctoral degree. The Health Prevention Corps complements these fellowships and targets a largely untapped market-- those at the entry-level who have recently completed a bachelor’s degree in sciences related to epidemiology, environmental health, or laboratory science—to try to draw them into public health careers. The Health Prevention Corps is an important effort for CDC to attract new talent to public health.

- 2. I was pleased to see that your budget justification states that the CDC will use increased funds in the area of Prevention, Detection and Control of Infectious Diseases in order to build the workforce capacity, laboratory facilities and skills sets within state and local health departments. However, I see that the Epidemiology and Laboratory Capacity (ELC) program is flat funded. Could you explain how the ELC and other CDC initiatives will interact to support state labs?**

CDC has invested in creating a flexible and adaptable infrastructure to be able to identify and respond to emerging infectious diseases. This infrastructure creates the core capacity needed at the state and local level to detect and control infectious disease threats by building a sufficient and competent workforce, laboratory facilities and capacities, and epidemiologic, statistical, and communication skills. This infrastructure serves as a foundation for many of the infectious disease activities supported by CDC and enables state and local health departments to build capacity and address infectious diseases in a more coordinated and efficient way.

The Epidemiology and Laboratory Capacity (ELC) for Infectious Diseases cooperative agreement program builds epidemiology, laboratory, and information system capacities in all 50 states, six local health departments, and two territories to assist frontline state and local programs to monitor, detect, and respond to new and emerging infectious diseases. For FY 2010, planned funding for the Epidemiology & Laboratory Capacity program is approximately \$55 million, which includes \$5 million in American Recovery and Reinvestment Act funds. However, because this program serves as a mechanism to provide grants to health departments for epidemiology and laboratory capacity activities funded by other CDC initiatives (i.e. food safety, antimicrobial resistance, influenza, etc.) the total ELC funding for FY 2010 will not be finalized until the end of the fiscal year. Similarly, total funding for FY 2011 for the ELC grant program will be available at the end of that fiscal year as well. The FY 2011 Budget includes an increase of \$20 million for emerging infectious diseases, which will support surveillance, and infectious disease laboratories and other key state and local health programs.

With this program, CDC will:

- Support and enhance state and local ability to detect, prevent, and control a broad spectrum of important infectious diseases including influenza, foodborne disease, vaccine preventable infections, and vector-borne diseases;
- Build infectious disease public health workforce capacity by providing reagents to the states, as well as laboratory support and laboratory training;
- Build and enhance state/local laboratory capacity by providing funding to purchase and maintain state-of-the-art laboratory technology, including equipment for molecular assays such as pulsed field gel electrophoresis (PFGE), reverse transcription-polymerase chain reaction (RT-PCR); and
- Implement cutting-edge information technology solutions that support rapid, secure, and accurate information exchange; diverse types of information; and linking of information among local, state, and federal public health agencies, healthcare facilities, and laboratories.

**3. I am also pleased to see the increase for the budget for health statistics, and that you will use this increase to improve the National Health Interview Survey. As you know, I have worked with colleagues over the past few years to increase our collective knowledge about health disparities, including LGBT health disparities. With the \$18 million increase in your budget, can you commit to adding a demographic question on the LGBT community to the National Health Interview Survey?**

There is a compelling need for better information on health disparities, including the health of LGBT populations. To continue to improve information on health disparities, high quality data from a national, representative sample that is large enough to allow researchers to conduct detailed analyses of the health of populations of interest is needed.

The National Health Interview Survey (NHIS) obtains data allowing for analysis of health disparities and is a potential vehicle for collecting data on LGBT populations. Prior experience with asking questions about sexual orientation in other national surveys has shown that it is essential to address the methodological issues that could impact this data collection. Pilot testing of the questions is also important to ensure that valid and useable data are obtained and plans have been developed to undertake this research and testing.

The FY 2011 budget request proposes increased health statistics funding to be directed to specific improvements in the NHIS as well as the National Ambulatory Medical Care Survey and the National Vital Statistics System. The proposed increase for the NHIS is intended to increase the sample size. This will allow HHS to obtain state and community estimates for most states and for large metropolitan areas. It will also provide for improved disparities data in general. We have not yet specifically identified funds for the methodological and pilot studies needed to add questions on the LGBT population or to incorporate the questions into the ongoing NHIS, but we are continuing to explore opportunities.

This department is committed to improving the health of all disparity populations, including the LGBT population, and will continue to pursue options that will allow us to expand data collections to achieve this objective.

**4. I have been working with NIH to learn what the Institutes are currently doing in terms of research into LGBT health disparities. I note that your proposed budget included an increase of nearly \$8 million for the Center that studies this issue. I'm aware that the IOM is undertaking an 18-month review of the state of the science on LGBT health research, but what work can NIH undertake in the meantime to demonstrate its commitment to tackling LGBT health disparities?**

NIH is supporting a number of important studies to advance the health of LGBT populations. In FY 2009, the NIH funded 272 grants, at just over \$239 million. These figures do not represent the full extent of the funded research related to LGBT health, however, because they include only those grant applications that specifically identified LGBT populations.

In addition to research funded by the National Institute of Allergy and Infectious Diseases targeting HIV/AIDS, the following are examples of the important research efforts underway in other areas:

- The National Institute on Drug Abuse is supporting research on the role of social networks in the sexual health of lesbian women to ascertain factors that may offer protection against sexually transmitted diseases;
- The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) continues its long history of research on how gender characteristics develop over time in girls with congenital adrenal hyperplasia, a

genetic condition that involve excessive or deficient production of sex steroids that can alter the development of primary or secondary sex characteristics in some affected infants, children, or adults.

- The National Cancer Institute is examining the molecular epidemiology of HIV and/or human papilloma virus in men to improve cancer screening accuracy.
- The National Center on Minority Health and Health Disparities is conducting research to identify best practices in reaching LGBT populations with health messages through a project on strategies to increase minority populations' participation in internet HIV prevention activities.

The NIH recognizes that it is critical to involve young investigators in these areas of research. The NICHD is funding research infrastructure for a training program for pre- and post-doctoral LGBT researchers, and the National Institute on Aging provided funding that allowed an early career investigator to move into HIV/AIDS research. NIH's budget proposal included a request for additional funding for NICHD's Center for Population Research. The funds would help support additional research on reproductive health, prevention of sexually transmitted diseases, and behavioral and social sciences research, issues that are also important to LGBT health.

In 2009, the National Institutes of Health (NIH) received inquiries from both Members of Congress and the research community about the range and status of currently funded NIH research on lesbian, gay, bisexual and transgender (LGBT) health, including research to identify important sexual orientation and gender identity-related health disparities. Noting that gaps in knowledge and research do exist, the NIH commissioned the Institute of Medicine to conduct a study and submit a report on "the state of knowledge regarding LGBT health, health risks and protective factors, and health disparities," with a particular focus on "the developmental process from childhood across the life span, in the context of family and social networks," and the effects of age, race and ethnicity, socio-economic status and geography. The IOM is charged with identifying research gaps, improved methodological approaches, opportunities (including training needs) and priorities for conducting research with the LGBT populations. The report is expected in the spring of 2011.

While many challenges remain to conducting research in LGBT populations, the NIH is looking forward to the IOM report and continuing to work with the research community to address the research gaps and opportunities in this area.

5. **I was concerned to see that the hemophilia program at CDC's Blood Disorders Division was zeroed out in the President's Budget, because this program provides critical support for hemophilia treatment centers which provide an excellent standard of care for people with bleeding disorders in Wisconsin and across the country. I see that a new "Public Health Approach to Blood Disorders" account was added. With the elimination of the hemophilia program, will CDC maintain its commitment to hemophilia treatment centers**

**and the other hemophilia outreach and education programs currently supported?**

CDC's FY 2011 request includes a proposal to realign the Blood Disorders program. Realigning CDC's approach to blood disorders will allow the Agency to truly address the public health problems facing the entire population of people affected with blood disorders. Support for Hemophilia Treatment Centers (HTC) will be included in this new initiative. We are not eliminating the HTC program; we are, instead, incorporating the program into a broader approach. Program activities are currently under review and will be considered for expansion or refocus to ensure our efforts are efficient, effective, and provide a measurable public health impact for the population of persons with blood disorders.

FY 2011 resources will support a portfolio of activities that include work to improve access and application of scientific information about blood disorders, to increase collaboration between members within the blood disorders community; and to advance science through surveillance and its application to public health efforts.

- 6. I know that the Administration is proposing to increase ADAP spending by \$20 million for fiscal year 2011, but I fear this is not enough – and not soon enough to help states in crisis now. What are we going to do in the meantime to get medications to these people who need them now? Would you support emergency funding for the ADAP program this year?**

As you know, ADAP is a critical program that helps provide access to medications for people with HIV/AIDS who have limited or no prescription drug coverage. We share your concern for getting medications to people in need now. The Health Resources and Services Administration (HRSA) is providing technical assistance to States to help them maximize all possible funding sources for these medications.

HRSA is also working with states to assure that they are providing assistance to clients who have no other way to pay for their drugs, such as by helping states obtain access to medications for their clients from pharmaceutical manufacturer's Patient Assistance Programs (PAPs). If additional funds are made available to address the waiting lists in states, we will work with the affected states to assure that these funds are used immediately to provide the medications to people in need.

**The Honorable Jim Matheson**

Secretary Sebelius, I want to share with you some priorities that I hope your department will continue to work with me on in the coming months.

**I. Lead in Plates**

As you reference in your testimony, the Department has made a significant commitment to securing our nation's food supply by increasing the budget for food safety efforts by \$327 million. I too support this goal and the hard work of my colleagues on this committee to pass important legislation last year.

As you know, the Food and Drug Administration regulates the lead levels of ceramic ware and has set acceptable levels of lead allowed in ceramic ware used in food preparation and currently has a safety warning designating ceramic items not intended for food use. However, there is currently no label alerting consumers that the ceramic products they purchased for food use/preparation (i.e. plates, cups, etc) contain any lead.

I sponsored an amendment that requires labels on plates and packaging for ceramicware/cookware containing lead for an intended functional purpose and sets up an educational program on its website to further educate consumers about these issues and about safe practices.

1. **Can I count on your office to continue to work with me to ensure that these measures are included in a final food safety bill and that you stand with me to better protect children and families from the potential problems caused by incorrectly fired ceramic ware and lead leaching from ceramics?**

I appreciate and share your concern about the health hazards posed by lead in ceramicware. To protect consumers, the Food and Drug Administration at HHS has established maximum limits for leachable lead in ceramicware. Pieces that exceed these limits are subject to recall or other enforcement action, such as refusal of admission into the United States for imported goods. These limits are based on how a piece of ceramicware is used, the type and temperature of the food it holds, and how long the food stays in contact with the piece. For example, cups, mugs, and pitchers have the lowest action levels because they can be expected to hold hot foods, e.g., coffee, or in the case of pitchers, to hold foods longer, allowing more time for lead to leach out of the glaze.

Commercial ceramicware manufacturers typically employ strict manufacturing controls to ensure that their ceramicware meets FDA's requirements. However, small potters often cannot effectively control their manufacturing processes to meet FDA's requirements for leachable lead. Therefore, FDA recommends that consumers who purchase ceramicware that is not commercially made should ensure that the ware is made using a non-lead glaze.

We share your interest in educating consumers about these hazards and would be happy to continue to work with you on this important public health issue.

## II. Comparative Effectiveness

**Secretary Sebelius, you've been clear that the goal of comparative effectiveness research is to improve the information available to a patient and his or her provider so they can make informed decisions about care. Some opponents of CER have raised concerns about the research may be used for other means.**

**2. As a representative of innovative teaching and research institutes, my providers want to know how will the Department assure that patients and providers have input into the research process? What steps do you see taking to achieve this?**

In order for Patient-Centered Health Research to be successful, it must be meaningful to patients and their health care providers, which means that both groups must be involved in every aspect of the research. The Agency for Healthcare Research and Quality (AHRQ) has many mechanisms in place to insure that stakeholder involvement occurs throughout the research process, which helps to ensure the relevance of the research to all of those making health care decisions. For example, AHRQ encourages stakeholders to engage in the following activities with respect to its patient-centered health research:

- Nominating research topics
- Identifying meaningful health outcomes
- Commenting on draft research questions before research has begun
- Commenting on draft Research Reviews and Comparative Effectiveness Reviews
- Providing expert input or scientific information to inform a report
- Participating in focus groups that help translate research findings for patients and clinicians
- Participating in inter-active listening sessions to provide focused comments on issues important to the Effective Health Care Program (the home of AHRQ's Patient-Centered Health Research), such as research topics, program structure, and scientific methods.

In addition, as you may know, AHRQ supports the Effective Health Care Program which funds individual researchers, research centers, and academic organizations to work together with AHRQ to produce comparative effectiveness research for providers, patients, and policymakers. More information about opportunities for stakeholder input into the Patient-Centered Health Research process is available on the Effective Health Care Program Web site at [www.EffectiveHealthCare.ahrq.gov](http://www.EffectiveHealthCare.ahrq.gov).

Finally, AHRQ is using Recovery Act funds to establish and support a Citizen Forum on Effective Health Care in order to formally engage the public, including patients and providers, through a variety of transparent and inclusive mechanisms, at the critical stages of identifying research needs, study design, interpretation of results, development

of products, and research dissemination. Funds will be used to develop formal processes for input, convene citizen panels, and convene a Workgroup on Patient-Centered Health Research to provide formal advice and guidance to the program. Funds will also support programs to enhance citizens' awareness of the availability of this scientific evidence in health care decision-making. These programs, developed under the guidance of the Citizen Forum, will include town hall meetings, Web-based information exchange, and community-based grassroots awareness efforts.

### **III. Pedigree**

**I, along with my colleague Rep. Buyer, am working on legislation to ensure safety in our nation's drug supply chain. As you may be familiar, CA enacted legislation last year to tackle this issue and I believe that this is an issue where we need a uniform, national system to ensure that we do not have a patchwork of regulations. This is a proactive piece of legislation to further build on what works in our current system and adapt to the new, and high tech ways counterfeits enter drug distribution channels around the world.**

#### **3. Will your office continue to work with me on creating a framework that ensures a safe and secure drug distribution channel?**

We appreciate your efforts and the efforts of Representative Buyer to ensure safety in our nation's drug supply chain. As we have indicated in past correspondence, we support the intent of the discussion draft that you provided and look forward to continuing to work together as your legislation takes shape. Thank you for the opportunity to work with you on this critically important issue.

### **IV. H1N1**

**Secretary Sebelius, I agree with your assessment that the H1N1 pandemic served as a "wake-up call," and I am pleased that you are in the process of reviewing our national readiness and response efforts. As we assess the adequacy of our vaccine production infrastructure, we must also evaluate the availability of the drug delivery devices, including needles and syringes, which are critical to administering vaccines.**

#### **4. Given that the supplemental funding approved last year remains available for pandemic influenza activities, have you considered using your discretion to direct any excess supply of drug delivery devices under contract for the current H1N1 immunization campaign to the Strategic National Stockpile to ensure that we are better prepared for future events?**



We appreciate your support for pandemic preparedness with the FY 2009 Supplemental Appropriations Bill and the continued interest you have shown in making our programs successful.

Regarding your request to direct any unused drug delivery devices from the 2009 H1N1 response, like syringes and needles, to the Strategic National Stockpile (SNS), options for their disposition will be developed and reviewed. Storage of these supplies in the SNS, as you suggest, is one option that will certainly be considered.

HHS remains committed to the establishment of domestic infrastructure and medical surge capacity, including those for medical products. Fortunately, the U.S. has a manufacturing surge capacity for syringes and needles that meets pandemic demands. However, we recognize that other events occurring simultaneously may negatively impact this capacity.

I appreciate your strong commitment to public health preparedness and look forward to continuing to work with you and your colleagues in Congress on these important issues.

**The Honorable Peter Welch and the Honorable Bruce Braley**

The Deficit Reduction Act of 2005 made serious changes to pharmacy Medicaid reimbursement, moving to average manufacturer price (AMP) to set federal upper limits for generic drugs. As part of healthcare reform legislation, both the House and Senate made changes to the AMP-based system, since several government studies have concluded that in many cases this system would reimburse pharmacies below their cost to obtain prescription medications. This low reimbursement for prescription drugs is compounded by the fact that pharmacy dispensing fees are also below pharmacies' costs to dispense prescription medications.

I am concerned that these factors, as well as the potential for states to make additional provider reimbursement cuts as a result of budget issues, will result in pharmacies leaving the Medicaid program. Community pharmacies play a critical role as primary health care providers in all communities across the United States and often serve as the only resource to millions of lower income Americans for their daily health care needs.

1. As you know, federal law (42 U.S.C § 1396a(a)(30)) requires Medicaid reimbursement be set at levels to ensure that Medicaid patients have the same access to providers as the general population. What steps is the agency taking to measure beneficiary access, and ensure that Medicaid patients maintain access to prescription drugs and pharmacy services?

We are currently limited in our ability to implement certain provisions of the current AMP regulation due to a preliminary court injunction. Though we cannot specifically comment on an issue of pending litigation, we agree that equitable and appropriate reimbursement to pharmacies for prescription drugs helps to ensure that Medicaid patients maintain access to prescription drugs and pharmacy services.

As you note, the recent health reform legislation passed by Congress would directly address this issue by amending the definition of AMP and increasing the reimbursement for generic drugs above the level set in the Deficit Reduction Act (DRA). We will continue to work with you and Congressional leadership to ensure that we have an effective Medicaid drug pricing program and ensure adequate access to prescription drug for all Medicaid beneficiaries.

**The Honorable Mary Bono Mack**

I wanted to first thank you for your commitment at the hearing on the 4<sup>th</sup> to bring together the HHS Inspector General and Administration for Children and Families to examine the use of Federal funds by a tribal TANF program operating in southern California. Below are further questions that may help to guide your internal review and help Congress to better understand the situation.

1. The Torres Martinez Tribal TANF program receives its annual federal award of more than \$20 million based on an estimated monthly caseload of 5,238 families. This caseload number was apparently set by both federal law (which calls for basing it on a formula using 1994 AFDC figures) and the tribe's contention to ACF that Native Americans were undercounted in Riverside and Los Angeles counties.

Yet in 2007, six years into the Torres-Martinez program, it was serving fewer than 400 families per month -- 7 percent of its initial projections. Despite this, the Torres-Martinez program's federal award was unchanged, and the program also received about \$15 million a year in grants from the state of California based on the federal caseload formula.

Today, the Torres-Martinez program's caseload is still only about one-fourth of what was projected when its program was formulated.

- a. Why has there been no examination of whether to reduce the Torres-Martinez program's annual award, given its far lower caseloads?

The caseload used to establish the amount of Federal funds for this grant was based on the State-reported FY 1994 AFDC caseload and expenditure data, adjusted in negotiations between the State and Tribe and agreed to by both parties. This caseload is not an "estimated monthly caseload" in the sense of being a minimum requirement, projection, or target number of cases to be served. The amount of State maintenance of effort (MOE) funds provided is determined solely by the State and is not fixed to any Federal formula.

In the same manner that the Federal funds received by a State, also set at the FY 1994 level, have not been reduced in spite of the dramatically reduced caseloads being served, once Tribal TANF block grant awards are established they are not adjusted based on current program caseload levels.

- b. Has there been a consideration by ACF of whether the Torres-Martinez, a tribe of about 400 members whose reservation is in a remote part of the Southern California desert, should no longer operate a program in urban Los Angeles County, the nation's most populous county by far, some 130 miles away from the tribe's

**reservation? Especially given the program's failure to increase its participation rates to expected levels over the course of nearly a decade? Why or why not?**

We have been working to help the Tribe develop an approach to expand services throughout its service area in a prudent manner. This has been done with consideration of the ability of needy families within the Tribe's target population in Los Angeles to continue receiving services from Los Angeles County until such time as critical program and financial deficiencies were addressed and program expansion could proceed in a well planned manner.

**c. Has there been an examination by ACF of whether the Torres-Martinez program is failing in its mission, given that nearly a decade into the program, it is reaching far fewer Native American families than anticipated? Why or why not?**

Although the base caseloads were derived in conformity with the statute and regulations for identifying funding levels for tribes, as previously noted, the historical FY 1994 caseload and expenditure data are not viewed as a minimum required or target level for families to be served. One key consideration under TANF has been the extent to which States and Tribes could use these funds to address underlying barriers to self-sufficiency and to provide work supports, as opposed to only providing cash support to needy families. ACF has worked with the Tribe to promote a range of supportive/barrier removal/family preservation services designed to achieve the Tribe's own goals for promoting the well being of the children and families they serve. The Tribe indicates that it has expanded beyond the cash assistance caseload to a larger population for whom supportive/barrier removal/family preservation services have been made available. We anticipate a similar approach in Los Angeles County. The Tribe has been responsive, at both the TANF program level and the Tribal Council level, in providing information on current and planned program activities and enhanced internal oversight mechanisms.

- 2. ACF imposed a more than \$1.5 million penalty on the Torres-Martinez tribe for misuse of TANF funds in fiscal years 2002 and 2003. The 2002 portion of the penalty -- \$625,380 -- was to be paid in escalating quarterly installments commencing in September 2006 and concluding on Sept. 30, 2009. The 2003 portion of the penalty -- \$912,500 -- was to be paid in escalating quarterly installments starting in March 2008 and paid in full by Dec. 21, 2011.**

**In an Aug. 12, 2009, letter to ACF Director of Office of Family Assistance Sidonie Squier, Torres-Martinez Tribal Chairwoman Mary L. Resvaloso said the tribe had "diligently made payments, in good faith, for a total of \$250,000 to date."**

**But according to ACF spokesman Kenneth Wolfe, the tribe has made a total of one payment for both penalties, for \$275,000, on Sept. 22, 2009 — more than a month after Resvaloso's letter, and three years after payments were supposed to start.**

- a. According to Wolfe, ACF agreed to reduce payments required of the Torres-Martinez on the penalty following a January 2008 letter from tribal officials citing financial hardship. The payments were reduced to \$25,000 per quarter to cover both the 2002 and 2003 misuse of TANF funds penalties. But the tribe never made even the reduced payments.**

TANF penalty regulations require that the Tribe repay its penalties by substituting its own funds to cover expenditures that it would have made with Federal TANF funds. Based on instructions from ACF, the Tribe was depositing its own funds to its TANF grant account, and they were available for use. However, the Tribe did not have sufficient expenditures to offset the TANF penalty amount. Therefore, ACF requested that the Tribe forward the funds it had set aside to the HHS Program Support Center. This is the payment made in September 2009. In early March, Torres Martinez sent an additional \$75,000; they are up-to-date on their reduced quarterly installment plan for the 2002 penalty and \$50,000 in arrears on the 2003 penalty.

- b. Why did ACF not take action when the tribe for years was not paying its penalty payments? This appears to have been the only imposition on the tribe for misspending at least \$1.5 million in taxpayer funds intended to help the needy, but it was no imposition at all, in that the tribe was at no time paying the penalty.**

Please see the answer above. The Tribe had deposited its own funds, as required by ACF, into its TANF fund.

- c. What actions can ACF consider if the penalty payments continue to be unpaid? And is the agency considering them?**

The total penalty amount for FY 2002 and FY 2003 was \$1,543,888 (\$625,388 for FY 2002 plus \$912,500 for FY 2003); to date, the Tribe has paid back \$350,000. The Tribal TANF regulations provide that should the Tribe fail to make the penalty payments, additional penalties may be applied and the annual grant award reduced.

Recently, the Tribe, as permitted by the Tribal TANF regulations, requested that ACF consider reducing the Tribe's current annual Tribal Family Assistance Grant

(TFAG) for FY 2010 by the total balance due, plus an additional two percent penalty to be applied to the total TFAG for FY 2010. The total balance due is \$1,589,064. This amount is based on the following calculation: \$1,537,888 (the full penalty amount for FY 2002 and FY 2003) minus \$350,000 (the amount paid directly by the Tribe) plus \$401,176 (the amount of the additional penalty of two percent). ACF has accepted the request and the balance due will be taken from the Tribe's TFAG for the two remaining quarters of FY 2010.

3. **Tribal officials, and to some extent California and federal officials, have indicated the Torres-Martinez Tribal TANF program's problems are largely problems of the past. That the tribe has made progress in its areas of deficiency in recent years, particularly because new management and professional staff was put in place. But the tribe continues to have material weakness findings in every annual audit.**

And a review by The Desert Sun of auditors' findings year to year seems to show the same major problems recurring and many of the same promises by tribal officials that fixes were in place or on the way. (See here: <http://www.mydesert.com/article/20100117/NEWS06/1160359/TANF+Timeline++Promises+made++yet+problems+persisted> )

- a. **What actions did ACF take when the same major problems were occurring in the Torres-Martinez Tribal TANF program every year, including an inability to reliably track how the program spent and disbursed money, and whether it was following federal laws, rules and guidelines? Do you believe those actions were sufficient?**

ACF has engaged in on-site program and financial oversight and meets periodically with the Tribe in the Regional Office to follow-up on outstanding program and financial issues. We believe that these efforts have facilitated significant progress by the Tribe in administration of the program and ensuring compliance with pertinent laws and regulations.

4. **HHS's National External Audit Review Center issued alerts against the Torres-Martinez tribe every year from 2002 through at least 2006. The alerts detailed the significant findings of financial accountability problems within the tribe's TANF program. HHS's Office of Inspector General was carbon copied on each of those "NEAR Alerts."**

- a. **What actions were taken by ACF, by HHS and by the Office of Inspector General in particular as a result of these alerts year after year?**

Torres Martinez has submitted audits to the National External Audit Review Center (NEARC) that cover its operations through September 30, 2008. NEARC is a component of the Office of Inspector General (OIG). Through NEARC, OIG reviewed the 2002 through 2006 independent audit reports on the Torres-Martinez Tribal TANF program and referred to ACF the audit reports along with alerts describing the independent auditors' findings of internal control weaknesses. These alerts were also forwarded to OIG's Office of Investigations. Referral to the grant-making agency is OIG's typical practice, as the responsibility for imposing corrective action in response to single audit findings lies with the grant-making agency. OIG also referred to ACF information on allegations of misuse of grant funds by the Torres-Martinez Tribal program that OIG had received in 2003. ACF has worked with the Tribe to ensure it develops appropriate corrective action plans in response to the audit findings. Because of the Tribe's difficulty in retaining a stable management team, corrective actions have not always been implemented timely. The 2008 audit shows that a number of previous problems have been resolved.

**b. Why did the Office of Inspector General never do its own investigation of the Torres-Martinez Tribal TANF program, particularly after the most serious findings of mismanagement and waste in the 2002 and 2003 audits? What does OIG investigate if not this?**

The HHS Office of Inspector General (OIG) reviewed the 2002 and 2003 independent audit reports on the Torres-Martinez Tribal TANF program, and our National External Audit Review Clearinghouse (NEARC) referred to ACF the audit reports along with an alert describing the independent auditors' findings of internal control weaknesses. This is NEARC's typical practice, as the responsibility for imposing corrective action in response to single audit findings lies with the grant-making agency, i.e., ACF in this case. NEARC also referred to ACF information on allegations of misuse of grant funds by the Torres-Martinez Tribal program that OIG had received in 2003. OIG's understanding is that ACF imposed a corrective action plan on the program to address the internal control weaknesses. NEARC recently received a single audit report on the Torres-Martinez Tribal TANF program for 2008, and we are currently reviewing this report.

5. **A 2002 draft audit by the Torres-Martinez's auditor, The Sells Group, stated, "An HHS 'auditor' from San Francisco conducted on-site visits, apparently without looking at documentation, and applauded everything he was told. But if he had looked at the substance rather than the form, he should have been more critical ... management was directly involved in putting a positive spin on very high-risk behaviors, and the consultants responded to that by playing down the risks and playing up the accomplishments."**

This account seems supported by an e-mailed shared with The Desert Sun by former Torres-Martinez TANF program executive director Virginia Hill. The e-mail, dated Jan. 23, 2003, shows it sent to Hill by James Henry, then a tribal program specialist for Administration for Children and Families' San Francisco office.

The e-mail discussed Henry's on-site visit to the Torres-Martinez tribal welfare program in 2002. (Bolding added.)

"Since there are no official or unofficial review tools, the trip report is the format we currently use," Henry stated.

"It was a good opportunity to see what the program has been doing and the benefits being provided to native communities ... Based on my initial visit, the program is progressing well."

**a. Are there still "no official or unofficial review tools" of Tribal TANF programs by ACF?**

Tribal TANF, like State TANF, is a block grant that is governed by title IV-A of the Social Security Act. The single audit is the primary mechanism that we have under the law to monitor State and Tribal TANF operations.

The single audit is generally conducted by a private audit firm hired by the Tribal TANF grantee. The audit firm looks at a myriad of administrative, program, and financial operations to ensure that the Tribal TANF grantee is operating in compliance with the Social Security Act, the implementing regulations at 45 CFR Part 286, the approved TTANF plan, and the appropriate financial management regulatory provisions at 2 CFR and 45 CFR Part 92.

In addition, the single audit mechanism has been supplemented with onsite program and financial reviews conducted by our Regional Office staff. These onsite reviews also provide technical assistance to our Tribal TANF grantees when problems or operational deficiencies are brought to our attention.

**b. How does ACF review and determine the effectiveness of Tribal TANF programs?**

In addition to the methods listed in the previous answer, the program also submits monthly work participation reports on a quarterly basis and quarterly financial reports.

**c. Under the criteria cited in b. , is the Torres-Martinez Tribal TANF program effective? Why or why not?**



Under the TANF statute, HHS does not have general authority to determine “effectiveness” of efforts by States and Tribes. Rather, HHS’ authority is limited to determining whether States or Tribes are subject to penalties for specified violations, like failure to meet the work participation rate. When a state or tribe fails to achieve applicable participation rate targets, a penalty may be imposed. The Tribe has not been assessed any such penalties. The Tribe failed to achieve its negotiated participation rates in FY 2004. However, as provided in the regulations, the Tribe submitted a corrective compliance plan and achieved its required rates in FY 2005. As noted earlier, ACF has also worked with the Tribe to promote a range of supportive services designed to achieve the Tribe’s own goals for promoting the well being of the children and families they serve.

6. **The Desert Sun reviewed the Form SF-SAC reports for Tribal TANF programs nationwide, through the Federal Audit Clearinghouse. Forty-four of the 52 programs nationwide had forms where TANF grants were discernable. Of those, more than one-third of programs had either significant deficiencies, material weaknesses or both in each of their past three audits. Nearly half of the programs nationwide had such audit findings in at least two of the past three years.**

- a. **Does this indicate to ACF that there may be a more systemic problem going on? Is there a need for more federal involvement with tribes to ensure their financial accountability with taxpayer funds?**

Section 409(a)(1) of the Social Security Act, which was amended with the enactment of welfare reform in 1996, requires the audit process to be used as our primary oversight vehicle for the various TANF programs operated by States, DC, Guam, Puerto Rico, the Virgin Islands, federally recognized Indian Tribes and Alaska Native organizations. The audit process along with the TANF penalty process (which is also contained in Section 409) provides for the resolution of adverse audit findings with an emphasis on the implementation of corrective actions to remedy any identified operating deficiencies. The correction of these deficiencies is a worthwhile goal and the Tribal TANF grantees that follow our audit compliance supplement have been responsive to this process. Moreover, these Tribal TANF grantees are sensitive to adverse audit findings and routinely ask for technical assistance in order to implement and operate efficient and effective systems. In fact we have established mechanisms that provide technical assistance to our Tribal TANF grantees and we intend to continue in this important initiative.

**The Honorable Lee Terry****1. Given the overall budget crisis and calls for across the board cuts, does the current request reflect any shift in HHS spending priorities in the near, mid, or long term, especially with regard to medical countermeasures directed at Category A biological threats?**

The Department of Health and Human Services remains committed to protecting the American people through developing medical countermeasures to biological threats. The FY2011 Budget Request for the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR) is \$476,194,000, representing an increase of \$135,663,000 above the FY 2010 funding level. This funding will support advanced research and development of the highest priority medical countermeasures among the 12 biological threat agents and radiological/nuclear threats identified in the PHEMCE Strategy and Implementation Plans, including Category A biological threats such as anthrax, plague and tularemia.

The BARDA budget request for FY 2011 reflects the efforts of BARDA/ASPR, in coordination with the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), and the Department of Defense to identify and fund only those programs mature enough for advanced research and development. The near and mid term priorities include anthrax, smallpox, radiological and nuclear threats, and broad spectrum antimicrobials. Working under the Integrated National Biodefense Portfolio, ASPR/BARDA, NIH/NIAID, and DoD will coordinate efforts to support programs for other high priority threats that are at earlier stages of development. This will ensure a smooth transition to ASPR/BARDA's advanced research and development portfolio in the long term.

Additionally, the Centers for Disease Control and Prevention (CDC), with guidance from BARDA and the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE), will continue to purchase, warehouse, and manage medical countermeasures necessary for treating affected populations, preventing additional illness, and providing medical supplies and equipment in response to a catastrophic public health event. CDC will also continue to work with FDA and the FDA shelf-life extension program to extend the usable life of many countermeasures.

**2. Specifically with regard to anthrax, it is important that the United States maintain an adequate reserve of licensed FDA-approved vaccine in the Strategic National Stockpile, a fact made all the more clear through the comments of recent remarks by the WMD commission and others about our domestic preparedness. Is it your intent to continue purchasing the entire supply of approved anthrax vaccine in an effort to achieve protection for 75 million individuals?**

Anthrax vaccine absorbed (AVA or BioThrax®) is the only licensed vaccine to prevent anthrax infection. HHS and DoD together have been purchasing nearly all of this anthrax vaccine manufactured each year by Emergent BioSolutions. Under contracts with ASPR/BARDA, Emergent delivered has 28.75 million doses of vaccine to the Strategic National Stockpile (SNS). In 2008, the procurement of the vaccine was transitioned to the Centers for Disease Control and Prevention (CDC) and SNS, which awarded a contract for delivery of 14.5 million doses of vaccine; deliveries are currently ongoing under that contract.

Studies have supported an extension of the expiry dating from 3 to 4 years for the Emergent anthrax vaccine product, which decreases the cost burden of maintaining the anthrax vaccine stockpile. Emergent also continues to generate data to support FDA approval for a post-exposure prophylaxis indication. Finally, HHS remains committed to the development of next generation anthrax vaccines.

**3. Regarding funds expended for new countermeasure development, it is essential that HHS use these funds efficiently and effectively which can be achieved by not letting the development process for new countermeasures become a long, extended one. My understanding is that while the development of the next generation anthrax vaccines has involved multiple candidates to increase likelihood of success, HHS has instead of conducting a competitive review, made a sole source award to only one of the developers. What steps is HHS taking to ensure that we do not place our reliance on any single company or approach? Will HHS be providing the needed funding to multiple candidates?**

The Department remains committed to the development of medical countermeasures (MCM), including anthrax vaccines, from multiple suppliers, through a full and open competitive contractual process that complies with the Federal Acquisition Regulations. Including many next generation anthrax vaccine candidates in the process will help ensure that several candidates mature and meet HHS and FDA requirements.

In February 2008, the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary for Preparedness and Response (ASPR) released a full and open competitive Request for Proposals (RFP) under Project BioShield, for late stage development and acquisition of rPA anthrax vaccine. A Project BioShield RFP was intended to take mature medical countermeasures at late stage development, and support them through the final safety and efficacy testing, to achieve licensure within a Project BioShield statutory maximum of up to 8 years and deliver 25 million vaccine courses to the Strategic National Stockpile.

In accordance with the HHS Acquisition Regulations, multiple comprehensive technical reviews of the proposals were conducted. Despite multiple proposal revisions and site visits, the Source Selection Authority within HHS determined that there were no Offerors that could meet the U.S. Government's statutory, scientific, and technical requirements. Therefore, ASPR/BARDA cancelled the RFP on December 7, 2009. Awarding contracts

to candidates that were deemed not mature enough would present an unreasonably high risk of failure for both prospective Contractors and the U.S. Government.

ASPR/BARDA issued on December 7, 2009, Special Instructions to an existing full and open competition through a Broad Agency Announcement (BAA) solicitation, which called for proposals for advanced development of next generation anthrax vaccines. Multiple proposals were received by the Feb. 2, 2010 deadline. The technical review process is underway and ASPR/BARDA expects to award contracts in 2010. Additionally, another proposal was received recently by ASPR/BARDA in response to a separate BAA under full and open competition for innovation of anthrax vaccines.

In late February 2010, HHS modified an existing contract with Pharmathene to increase the funding level on the contract for development and clinical product manufacturing activities within the scope of the original contract awarded by NIH. The ultimate goal of the original contract was to produce an rPA anthrax vaccine using a validated manufacturing process. Funding under the current contract modification funds those activities. Therefore, this was not a sole source award but a modification of an existing contract. The active ASPR/BARDA solicitation for advanced development of next generation anthrax vaccines is a full and open competition.

**The Honorable Michael Burgess M.D.**

1. **Madam Secretary, it has been over a year that Centers for Medicare/Medicaid Services has gone without an appointed head administrator, with all due respect, how can CMS properly function without a confirmed Administrator? Medicare and Medicaid are the largest insurance companies in the country and 51% of the Health and Human Services proposed budget is supposed to flow through CMS, how are decisions being made for the programs when there is no director? The Obama Administration has had more than a year to appoint a new director, have you (or) why have you not advised President Obama to naming a new Director?**

During the past year, two outstanding health policy leaders, Jonathan Blum and Cindy Mann, have been running Medicare and Medicaid. Under their leadership, CMS has helped serve millions of Americans and undertaken landmark efforts to fight fraud, help enroll children in the Children's Health Insurance Program and Medicaid, and distribute billions in Recovery Act resources to States.

In February 2010, Marilyn Tavenner, Dr. Peter Budetti and Tony Rodgers joined CMS as Principal Deputy Administrator, Deputy Administrator for Program Integrity, and Deputy Administrator for Strategic Planning, respectively. Their knowledge and experience gives us more resources to enhance our efforts to fight fraud and waste and to increase our focus on improving quality for our beneficiaries.

I also believe it is important to look at all that CMS has accomplished in this Administration. CMS has continued to issue regulations – and on time. The deadline was met for such important payment regulations as the physician fee schedule and the HITECH regulations that outline meaningful use and incentive payments for electronic records.

CMS has continued to make decisions and issue guidance, like the compensation requirements for agents and brokers that sell Medicare Advantage plans and helped ensure that beneficiaries who needed to change their Medicare Advantage or Prescription drug plans had the tools and information they needed to make those changes.

CMS met the statutory deadlines for Medicare Advantage reimbursement rates and is issuing guidance to states implementing provisions of the Recovery Act and the Children's Health Insurance Program Reauthorization Act, and before the end of the year, provided performance awards to a number of states that are actively reaching new CHIP eligible families and children.

CMS was one of the first agencies that made funds available under the Recovery Act – funds to allow states to continue to provide health care coverage to the most vulnerable Americans through Medicaid.

We have accomplished a great deal, and I'm confident we will continue to move forward in the years ahead.

2. **I strongly support a new \$400 million initiative included in the budget that will allow for private capital investment in low-income communities that are high investment risks. The funds would be divided between U.S Department of Agriculture, Health and Human Services and the Department of Treasury. Specifically, the budget includes \$250 million in New Market Tax Credit allocations to spur private supermarket investments in underserved communities. Currently, there are a record number of people using food stamps; however many times grocery stores are not available within reasonable location to food stamp users. With this program in the budget, the New Market Tax Credit allocations could create jobs, better neighborhoods, address obesity and lower cost to the Medicaid program. This is an issue that I think is critically important and while not under the direct jurisdiction of this Committee I will urge the greatest oversight of this program if it is appropriated. Secretary Sebelius, how do you foresee the coordination of this new proposed program as well as your expected results? How do you plan to design and implement this program and create measures for its evaluation – assuming the President's budget request is granted?**

The Department of Health and Human Services specializes in community-based efforts to improve the economic and physical health of people in distressed areas. While the bulk of the \$400 million Healthy Food Financing Initiative will be administered at the Department of Treasury, such as the New Market Tax Credit, or at the Department of Agriculture, HHS will dedicate up to \$20 million in Community Economic Development (CED) program funds to the Initiative. Through the CED program, HHS will award competitive grants to Community Development Corporations that support projects to finance grocery stores, farmers markets, and other sources of fresh nutritious food. These projects will serve the dual purposes of facilitating access to healthy food options while also creating jobs and business development opportunities in low-income communities, particularly since grocery stores often serve as anchor institutions in commercial centers.

The existing CED program utilizes three indicators in the annual Report to Congress to measure progress or success. The indicators are: 1) the number of jobs created; 2) the number of businesses created or expanded; and 3) the amount of non-CED funds secured or leveraged by grantees in addition to their CED award to implement the proposed project. Grantees often secure additional non-CED funds to implement their project; these funds are not required by statute but may be helpful to execute the project. In addition to these established measures in the CED program, the Department is working with other agencies to develop evaluation measures for the initiative across programs.

- 3. I feel that medical liability reform is strongly needed within the healthcare system. Why is liability reform, including limitations on non-economic damages not included in any of the healthcare reform bills passed by Congress? Currently, quality patient care is at high risk due to excessive liability costs placed on health care providers. Lawsuits against healthcare providers are hindering access to care and many doctors are abandoning high-risk procedures. Medical liability reform would help to provide more quality care for patients and more reassurance for doctors. Not only is a strong majority of the public in favor of medical liability reform, reform would also control premiums and increase the availability of medical professionals, especially in high-risk specialties. If President Obama is serious about reforming our medical justice system, will he advocate for comprehensive liability reform?**

I agree that our medical liability system needs to be examined to ensure that it meets four goals: putting patient safety first and working to reduce preventable injuries; fostering better communication between doctors and their patients; ensuring that patients are compensated in a fair and timely manner for medical injuries, while also reducing the incidence of frivolous lawsuits; and reducing liability premiums.

President Obama and I both recognize the importance of an effective medical liability system to promote patient safety as well as balance the interests of providers and patients. As a first step towards this goal, in September 2009, the President announced his proposal to invest in innovative strategies to better manage medical liability claims. In response to the President's directive, HHS committed \$25 million for this three-pronged initiative, which includes (1) a review of previous reform models to better inform our efforts; (2) grants for up to three years to jump-start and evaluate evidence-based patient safety and medical liability demonstrations; and (3) one year grants to support state planning efforts for medical liability and patient safety models.

The Agency for Healthcare Research and Quality (AHRQ) recently completed the review of previous reform models, which demonstrated the need for further study of the impact of various reform options, and the need for states and health systems to be able to innovate in this regard. AHRQ has completed the process of requesting applications for the planning and demonstration grants to be awarded under this initiative, and they are currently undergoing scientific peer review. AHRQ anticipates that it will make funding announcements of grantees by this summer.

Finally, HHS will continue our patient safety and medical liability efforts as we implement additional state demonstration programs to evaluate medical liability systems, as authorized and appropriated in the Patient Protection and Affordable Care Act. This provision authorizes an additional \$50 million over five years to support states with planning and demonstration grants, as well as evaluations to learn more about what elements work together in promoting patient safety and improving state medical liability systems.

- 4. The President's FY 2011 Budget includes passage of health care reform which states that when passed, it will reduce the deficit by \$150 billion from the years 2011-2020. Can you explain why this figure does not align with either the CBO score of the House or the Senate bill?**

The most recent CBO score of March 20, 2010 based on the Senate bill and the proposed reconciliation changes shows deficit reduction of \$143 billion between 2010 and 2019. The \$150 billion in savings provided earlier this year was based on the average receipts of the House and Senate bills, the average net outlays, and then trended forward to 2020 to provide a 10 year window from 2011.

- 5. The way the Presidents budget is presented, the placeholder manner of health reform hides the growth in government that would result from either the House or Senate bill. Once transparency is applied to the bill it is obvious that when fully implemented, the health reform proposal does not include the \$2.3 trillion in new spending over 10 years in the Senate bill and \$3 trillion in new spending in the House bill. Why is that?**

The report issued by CBO on March 20, 2010 makes clear the investments and savings attributable to health reform result in \$143 billion in net savings. The budget was developed over many months prior to the passage of health reform when many policies were still under consideration. As a result, the Administration was unable to include specific policies in the proposed budget. Now that health reform has passed, we will work diligently to make it a success.

- 6. Based on the information we received from past findings, have the Medicare Actuaries produced any new findings on the proposed Medicare budget and health reform? Do you mind detailing any discrepancies?**

The CMS Office of the Actuary (OACT) last released an analysis of the Senate-passed health reform bill on January 8, 2010. On the basis of that bill, the Actuary found that health reform will extend the life of the Medicare Trust Fund by 9 years.

The President's FY 2011 Budget Request included an underlying assumption that health insurance reform would be enacted, and therefore, showed deficit reduction totaling \$150 billion in FY 2011 – FY 2020, based on the CBO estimates of the "average budget impacts of the House- and Senate-passed health care reform bills, extrapolated to 2020 and adjusted to remove the effects of four provisions already included explicitly as 2011 Budget proposals." It is not uncommon for CBO and OACT estimates to vary slightly, due to minor differences in economic assumptions and scoring methodology.

- 7. In recent press reports, it has been indicated that House and Senate Democrats are again working behind closed doors on a reconciliation strategy to make**



**changes to the Senate bill. Press reports speculate that the package could cost as much as \$300 billion in new spending. If this health reform package is being compiled, why have we heard nothing from budget committee? It seems obvious from press reports that in order to have full usage of the health reform placeholder, Democrats are attempting to pass the bill through quiet compromise. Furthermore, if this is true, why does press seem to have more information than the House and Senate Republicans?**

The President posted a proposed package of amendments to the Senate bill on February 22, 2010. This was followed by 7 hours of bipartisan public discussion on C-Span. The final reconciliation package, reflecting the President's proposal as well as ideas raised by Republicans in that discussion, was posted online on March 18, which was 72 hours before any votes occurred. The CBO score posted on March 20 showed \$143 billion in deficit reduction, \$25 billion more deficit reduction than that achieved the Senate bill. The \$143 billion in savings is not a placeholder but the final score of the legislation as passed by the House on March 21, 2010.

- 8. How do you find it fiscally responsible to claim the effects of health reform legislation when the bills considered by Congress remain controversial? This is not a bipartisan policy or a shift in payment rate- it is 2,000 pages of controversy. The budget assumes passage and at the same time (based on CBO scores of the bills we do have) seems to fudge potential costs, is that not misleading at best?**

This legislation has undergone the most intensive scrutiny of any legislation in memory, including weeks and months of televised debate through Committee hearings, mark-ups, and floor debate. The savings in the first decade are projected to increase to about \$1 trillion in the next decade and savings are projected to continue into the following decades.

- 9. The President has called for a freeze on non-defense discretionary spending. There is no doubt that the Departments budget needs to reflect this net freeze as well. Can you concur and explicate that the budget does in fact emulate this freeze? Obviously, some accounts would require an increase in expenses which, in turn, would require a more significant decrease in other accounts. Please clarify for this committee which accounts in your Department will be targeted by this reduction?**

We have gone through the budget carefully and are eliminating the non-national security discretionary programs that don't work while investing in, and reforming, programs that do. We are investing in the things that help spur job creation and economic growth. The freeze would cut \$250 billion from the deficit over the next decade. Under the 2011 budget, non-security discretionary spending would fall to its lowest share of the economy in more than 50 years by the middle of the decade.

**10. Does your budget actually reflect a true physical comparison of year to year spending or does the budget reflect spending provided by the stimulus package? Isn't the \$1 billion increase in spending an addition to the \$10 billion provided in the stimulus bill for NIH research in 2009 and 2010? Essentially, NIH isn't getting a \$1 billion increase over last year- it is getting an increase on top of spending provided by ARRA.**

The \$10.4 billion provided to NIH in the American Recovery and Reinvestment Act of 2009 was a one-time appropriation in FY 2009 which NIH can obligate over two years through FY 2010. This raised the combined total appropriated to NIH for FY 2009 to \$40.95 billion. Because of their one-time nature, these ARRA funds were not continued and are not part of the FY 2010 appropriation of \$31.2 billion for NIH. Consequently, the \$32.2 billion requested for NIH in the FY 2011 President's Budget is an increase of \$1 billion over an FY 2010 base that does not include any ARRA funding.

**11. What details can you provide for how funding was spent at NIH, CDC, and HHS generally that was provided by the stimulus package? Can you provide audits to this Committee on how this money was disbursed?**

The American Recovery and Reinvestment Act provides HHS programs an estimated \$141 billion for fiscal years 2009-2019. While most provisions for HHS programs involve rapid investments, ARRA also includes longer term investments in health information technology. HHS plans to have obligated \$102 billion through FY 2010.

As of March 19, 2010, HHS has obligated \$72.4 billion in ARRA funding. The largest single program is the increased Medicaid Federal Medical Assistance Percentage (FMAP) which has obligated \$53.7 billion to States. NIH has obligated \$4.8 billion in scientific research, \$192 million in comparative effectiveness research, \$716 million in extramural construction, \$109 million in shared instrumentation, and \$68 million for buildings and facilities. CDC has obligated \$461 million for evidence-based clinical and community-based prevention strategies, \$204 million for section 317 immunization activities, and \$48 million to reduce healthcare associated infections.

The HHS Office of Inspector General performs audits on Recovery Act grant or contract awards, and these audits will be posted on Recovery.gov when they are complete.

Additionally, the Single Audit Act requires non-federal entities to have an annual audit of all their Federal grant or contract funds, including ARRA funds. Within 9 months from the close of an entity's fiscal year, the entity is required to submit their audit reports to the Federal Audit Clearinghouse (FAC), which is part of the Department of Commerce. Many non-Federal entities, particularly states, will submit their annual Single Audit by March 30, 2010 (for entities with fiscal year-end June 30, 2009). The FAC will prepare a report about the audit findings. If an audit report has no findings, the report remains with the FAC. When there are audit findings, the FAC forwards the report for action to the

relevant Federal agencies. To date, HHS has awarded more than 20,000 grants and contracts with ARRA funds. The large majority of these reports will have no findings.

- 12. Under the President's adjusted baseline, Medicare is projected to spend \$6.955 trillion over the next ten years (2011- 2020). This includes a \$371 billion proposal to fix the Medicare Sustainable Growth Rate (SGR) formula for physician reimbursement. In the adjusted budget however, the proposed Medicare fix is not paid for. With the Presidents current baseline, what reforms to the SGR do you envision and are there identified accounts to offset this policy?**

The Administration supports comprehensive but fiscally responsible reforms to the SGR payment formula. In the 2010 physician fee schedule final rule, we removed physician-administered drugs from the calculation of allowed and actual expenditures under the SGR, which could reduce the cost of fixing the scheduled cut by about \$130 billion over ten years. However, in the FY 2011 President's Budget Request, the Administration is not proposing any specific policy. Rather, to promote more honest and transparent budgeting, the FY 2011 Budget includes an adjustment totaling \$371 billion over ten years (FY 2011-FY 2020) to reflect the Administration's best estimate of the impact of presumed future Congressional action, based on Congress' repeated interventions to prevent scheduled reductions in physician payments in recent years. The Budget does not include an offset. The Administration chose to reflect this adjustment in the FY 2011 Budget because it more accurately reflects recent Congressional practice, acknowledges the important role Congress plays in appropriating funding, and allows for a more understandable and accurate budget process.

The Administration believes Medicare and the country need to move toward a system in which doctors face better incentives for delivering high-quality care, rather than simply more care. I look forward to working with Congress and other stakeholders to reform Medicare's payment methodology for physicians' services.

- 13. In addition, Medicaid is also projected to spend \$3.602 trillion over the next ten years (2011-2020). However, the President's budget does not show how Medicaid spending will increase as a result of enactment of health reform as it is proposed in his budget. Once again, why is health reform passage assumed for savings and not for costs?**

The savings that are achieved are net of costs. The CBO score makes clear that these savings accrue net of coverage expansions. The 2011 budget could not reflect those costs and savings since health reform had not passed when the budget was introduced.

- 14. The President's budget also includes a set of proposals intended to reduce waste, fraud and abuse in Medicare, Medicaid, and the Children's Health Insurance**

**Program (CHIP). Together these measures, aimed at improving program integrity, are expected to save \$37 billion over the next years. However, despite the increase in fraud prevention spending roughly the same numbers of cases have been pursued. I have heard the deficiency in pursued cases is not in investigation but in prosecution. Has Health and Human Services requested an increase in funding to supply more federal prosecutors with a background in health fraud? Obviously finding fraudulent cases greatly reduces the cost to the government but if we do not prosecute and prevent future cases, what is the point in wasting funds to find fraudulent cases?**

The FY 2011 President's Budget makes fighting fraud a priority by investing an additional \$250 million in new resources in 2011 as part of a multi-year strategy and supporting a package of legislative and administrative changes that will give HHS new tools that enhance program integrity oversight. Over ten years, these actions will result in over \$24 billion in estimated savings. This proposal includes a significant investment in support of the newly established joint HHS-DOJ Health Care Fraud Prevention and Enforcement Action Team (HEAT) initiative. The HEAT initiative is a joint effort between HHS and DOJ that has made fighting health care fraud a Cabinet level priority. It brings together the best minds and resources from two Departments to share best practices, prosecute criminals, and recover billions in taxpayer dollars.

Strike Forces are a key component of the HEAT enforcement strategy. The Strike Force teams use innovative investigation and prosecution methods to identify, investigate, and prosecute criminals involved in certain health care fraud schemes in a more expeditious manner. Each Strike Force team includes OIG and FBI agents and DOJ attorneys, supported by at least one designated CMS program expert in each Strike Force location. Through the HEAT initiative, DOJ is training prosecutors specifically for prosecuting health care fraud, and then relocating them to cities with a Strike Force team. Through HEAT, OIG and DOJ have expanded our Strike Force teams from two to seven locations. Collectively, Strike Forces have resulted in approximately 270 convictions, indictments of more than 500 defendants, and more than \$240 million in court-ordered restitutions, fines, and penalties.

In addition to efforts with HEAT, OIG has historically worked closely with DOJ to ensure that health care fraud investigations are successfully prosecuted. OIG investigators work with DOJ prosecutors on a case-by-case basis, while senior leadership coordinates efforts to ensure results are achieved. Moreover, OIG special agents and attorneys work with DOJ as Special Assistant United States Attorneys to assist in the prosecution of health care fraud cases. It is the results of these collaborative efforts that form the basis for successful outcomes. We will defer to DOJ in assessing the need and resources for additional prosecutorial efforts.

**15. The President's budget also includes an increase to expand and improve FDA's efforts to protect America's food supply. First, the budget includes a \$318 million increase in total program level which is over a 30 percent increase in**

**spending and an \$80 million increase in budget authority, which is a 6.2 percent increase. However, food safety legislation passed by the House and Senate has yet to be resolved. Which particular bill or policies in this pending legislation did you take into account when deciding on this increase?**

The President's budget request for FY 2011 includes FDA's Transforming Food Safety Initiative, which reflects President Obama's vision of a new food safety system to protect the American public. Some of the key components of the Initiative are new performance standards for food safety, expanded laboratory capacity, piloting a track and trace system for foods, strengthening the Agency's import safety program, and improving data collection and risk analysis. These initiatives are reflected both in the budget and in the food safety bills in the House and Senate.

The House and Senate food safety bills will provide important new authorities that provide the basis for the improvements noted above. They also provide authority for new user fees proposed in the budget for facilities registration and reinspections. The House bill (H.R. 2749) authorizes both of these fees, while the Senate bill (S. 510) provides for the reinspection fee and a recall fee, but not a registration fee.

The registration and reinspections fees in the President's budget will support the direct costs of registering and inspecting food manufacturing and processing facilities and conducting reinspections of facilities that fail an inspection. They will also help provide a consistent funding source to support other critical food safety activities, such as import review and product sampling.

